UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* DONNA RAUCH, MURIEL CALHOUN, BRANDY KNIGHT, KAREN MATHEWSON, AND TRACY HAWKINS Plaintiffs, v. OAKTREE MEDICAL CENTRE, P.C., FIRSTCHOICE HEALTHCARE, P.C., PAIN MANAGEMENT ASSOCIATES OF THE CAROLINAS, LLC, PAIN MANAGEMENT ASSOCIATES OF NORTH CAROLINA, P.C., LABSOURCE, LLC, PROLAB, LLC, PROCARE COUNSELING CENTER, LLC, and DANIEL MCCOLLUM, D.C. Defendants.	**No. 6:15-cv-01589-DCC** (Consolidated with No. 6:17-cv-01190-DCC No. 8:18-cv-02952-DCC) **JURY TRIAL DEMANDED**

UNITED STATES' CONSOLIDATED COMPLAINT IN INTERVENTION

By notice to the Court on March 3, 2019, the United States of America ("United States") intervened, in part, in the above-captioned cases. For its Complaint in Intervention, the United States alleges as follows:

INTRODUCTION

1. The United States brings this action against Defendants pursuant to the False Claims Act, 31 U.S.C. §§ 3729–3733 ("FCA"), seeking treble damages and civil penalties, and under common law and equitable theories of recovery.

2. Defendant Daniel McCollum is a chiropractor who owns and operates a network of pain management clinics, urine drug testing ("UDT") laboratories, and other businesses related to pain management. Defendant Oaktree Medical Centre, P.C. ("Oaktree") employs physicians who staff McCollum's pain clinics and perform laboratory services. Oaktree and other clinics owned by McCollum namely, FirstChoice Healthcare, P.C. ("FirstChoice Healthcare"); Pain Management Associates of the Carolinas, LLC ("PMA of the Carolinas"); and Pain Management Associates of North Carolina, P.C. ("PMA of North Carolina") all do business as Pain Management Associates ("PMA"). Hereinafter, these clinics will be collectively referred to as "PMA."

3. As described below, McCollum designed and executed a series of elaborate and extensive fraud schemes to maximize profits at his pain clinics and UDT laboratories at the expense of both patients and federal health care programs. In particular, Defendants offered improper financial incentives and illegal kickbacks to induce health care providers to incentivize referrals of UDT (including medically unnecessary and unreasonable UDT) to McCollum's laboratories, to provide medically unnecessary steroid injections, and to prescribe prescriptions for opioid drugs and lidocaine ointments that were not reasonable and necessary for the treatment of individual patients and that lacked a legitimate medical purpose.

4. More specifically, from at least January 1, 2011, through at least December 31, 2018 ("the relevant time period"), in violation of the FCA, Defendants submitted, caused to be submitted, and conspired to submit and cause the submission of tens of millions of dollars in false claims to federal health care programs, including the Medicare, Medicaid, and the TRICARE programs by (1) entering into financial arrangements with physicians related to the referral of, furnishing of, and submission of claims for UDT that did not satisfy the requirements

of an exception for, and therefore violated, the physician self-referral prohibition, 42 U.S.C. § 1395nn (commonly referred to as the "Stark Law"); (2) offering and providing illegal remuneration to health care providers to induce referrals to Defendant Labsource, LLC ("Labsource"), in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b; (3) billing or causing to be billed to federal health care programs claims for UDT that were not medically necessary and, in some instances, not performed; and (4) billing or causing to be billed to federal health care programs claims for steroid injection procedures and prescriptions for opioid and lidocaine medications that were not medically necessary or were without a legitimate medical purpose.

5. The Stark Law and the AKS arose out of concern by Congress that certain types of financial incentives, or items of value, could improperly influence or even corrupt the medical decision-making of physicians and other health care providers, resulting in federal funds being diverted to pay for goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. As detailed below, that is precisely what has happened here.

6. Defendants engaged in these schemes knowing that their actions were improper. When, for example, the Centers for Medicare and Medicaid Services ("CMS")—the agency within the Department of Health and Human Services ("HHS") that administers the Medicare Program ("Medicare") and the Medicaid Program ("Medicaid")—implemented a payment suspension on Defendant Oaktree for billing medically unnecessary UDT and steroid injections, McCollum simply transitioned his fraudulent schemes to, and pursued those schemes at, other entities that he owned and operated, including FirstChoice Healthcare and Labsource.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

8. The Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because each Defendant resides, previously resided in, and/or transacted business in the District of South Carolina during the relevant time period.

9. Venue is proper in the District of South Carolina under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b), because Defendants transact or transacted business in this district, and a substantial part of the events giving rise to this action occurred in the District of South Carolina.

PARTIES

10. The United States brings this action on behalf of HHS, which, through CMS, administers Medicare and Medicaid; and on behalf of the Department of Defense ("DOD"), which, through the Defense Health Agency ("DHA"), administers the TRICARE program ("TRICARE").

11. Relator Donna Rauch is a resident of South Carolina. From July 2013 to January 22, 2015, Ms. Rauch was employed as PMA's Chief Operations Officer ("COO") and Chief Financial Officer.

12. Relator Muriel Calhoun is a resident of South Carolina. From October 15, 2008, to February 25, 2015, Ms. Calhoun was employed as a Certified Medical Assistant and an Operations Manager for PMA.

13. Relator Brandy Knight is a resident of South Carolina. From March 1, 2010, to February 25, 2015, Ms. Knight was employed as a Clinic Coordinator for PMA.

14. In April 2015, Relators Rauch, Calhoun and Knight filed the first of these consolidated actions, *United States ex rel. Rauch, et al. v. Oaktree Medical Centre, P.C., et al.*, No. 6:15-cv-01589-DCC (D.S.C.), alleging violations of the FCA on behalf of themselves and the United States pursuant to the qui tam provisions of the FCA, 31 U.S.C. § 3730(b)(1).

15. Relator Karen Mathewson, who passed away in April 2019, was a resident of South Carolina. From May 4, 2015, to January 24, 2017, Ms. Mathewson was employed as a Credentialing Specialist and a Clinic Coordinator for PMA. In May 2017, Ms. Mathewson filed the second of these consolidated actions, *United States ex rel. Mathewson v. Dr. Daniel A. McCollum, et al.*, No. 6:17-CV-01190-DCC (D.S.C.), alleging violations of the FCA on behalf of herself and the United States pursuant to the qui tam provisions of the FCA, 31 U.S.C. § 3730(b)(1).

16. Relator Tracy Hawkins is a resident of South Carolina. From October 31, 2016, to August 6, 2018, Ms. Hawkins was employed as a PMA medical assistant. On October 31, 2018, Ms. Hawkins filed the third of these consolidated actions, *United States ex rel. Hawkins v. Pain Management Associates of the Carolinas, LLC, et al.*, No. 8:18-cv-02952-DCC (D.S.C.), alleging violations of the FCA on behalf of herself and the United States pursuant to the qui tam provisions of the FCA, 31 U.S.C. § 3730(b)(1).

17. Defendant Daniel McCollum is a chiropractor and resident of South Carolina. During the relevant time period, or portions thereof, McCollum owned and/or operated Defendants Oaktree; Labsource; FirstChoice Healthcare; PMA of the Carolinas; and PMA of North Carolina. McCollum also held a 50% ownership interest in Defendant ProLab, LLC ("ProLab"). During portions of the relevant time period, McCollum served as Chief Executive Officer ("CEO") of each of the aforementioned entities. Throughout his involvement with these

entities, including times when he did not formally serve as CEO, McCollum remained active in, and knowledgeable of, the management, operational, and sales decisions and activities of each of these entities.

18. Defendant Oaktree is a Professional Corporation authorized and existing under the laws of the State of South Carolina with its principal place of business in Greenville, South Carolina. McCollum has been the owner and sole shareholder of Oaktree throughout the relevant time period. Oaktree consists of a group of pain management clinics located throughout South Carolina. During the relevant time period, Oaktree employed physicians, physician assistants, and nurse practitioners who staffed Oaktree and other PMA clinics. In or around early 2011, McCollum established an in-house UDT laboratory within Oaktree to perform UDT for PMA's patients. During the relevant time period, Oaktree also performed UDT for other practice groups not affiliated with PMA. Oaktree furnished and billed UDT for Medicare, Medicaid, and TRICARE beneficiaries, among others. Oaktree received over $22 million from Medicare, $7.1 million from South Carolina Medicaid, and $1 million from TRICARE for UDT furnished between January 1, 2011, and December 31, 2018.

19. Defendant PMA of the Carolinas has been operated by McCollum throughout the relevant time period. Oaktree owns a majority share in PMA of the Carolinas. PMA of the Carolinas is a limited liability corporation authorized and existing under the laws of the State of South Carolina.

20. In or around May 2013, McCollum expanded his pain management business into North Carolina by purchasing Allayant Pain Management, P.C. from Dr. Brian M. Bothe. McCollum began operating his newly acquired North Carolina clinics through a newly formed professional corporation, PMA of North Carolina. Defendant PMA of North Carolina is a

limited liability corporation authorized and existing under the laws of the State of North Carolina. At times material to the allegations in this Complaint, Defendant PMA of North Carolina conducted business with individuals and entities in the State of South Carolina.

21. In or around 2013, McCollum established an independent UDT laboratory, Labsource. Defendant Labsource is a limited liability corporation authorized and existing under the laws of the State of South Carolina with its principal place of business in Greenville, South Carolina. McCollum is the owner and sole shareholder of Labsource. From roughly 2013 through at least December 31, 2018, Defendant Labsource provided clinical laboratory services for PMA clinics and other providers across the United States. Labsource received over $47 million from Medicare alone for UDT between January 1, 2013, and December 31, 2018.

22. In or around late 2013, McCollum entered into a business relationship with Defendant ProCare Counseling Center, LLC ("ProCare"), a substance abuse and addiction counseling center owned, at least in part, by Myron Moorehead. ProCare ostensibly provided substance abuse and addiction counseling services to PMA patients. Defendant ProCare is a limited liability corporation authorized and existing under the laws of the State of Georgia. At times material to the allegations in this Complaint, ProCare conducted business throughout the State of South Carolina.

23. In or around late 2013, McCollum established another UDT laboratory, ProLab. McCollum maintained a 50% ownership interest in Defendant ProLab, and Defendant ProCare maintained the other 50% ownership interest. Defendant ProLab is a limited liability corporation authorized and existing under the laws of the State of South Carolina with its principal place of business in Greenville, South Carolina. ProLab provided clinical laboratory services for ProCare

and PMA patients, including UDT. ProLab ceased operations in or around late 2014. ProLab received over $640,000 in reimbursements from Medicare alone for UDT services in 2014.

24. In or around June 2014, McCollum further expanded his pain management business by purchasing another group of pain management clinics in South Carolina, FirstChoice Healthcare. Defendant FirstChoice Healthcare is a Professional Corporation authorized and existing under the laws of the State of South Carolina with its principal place of business in Florence, South Carolina.

LEGAL AND REGULATORY BACKGROUND

I. The False Claims Act

25. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (a)(1)(C) conspires to commit a violation of subparagraph (A) [or] (B) . . ..

is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amounts range from a minimum of $5,500 to a maximum of $11,000. See 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, *47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty amounts range from a minimum of $11,181 to a maximum of $22,363. 28 C.F.R. § 85.5.

26. For purposes of the False Claims Act,

> the terms "knowing" and "knowingly" (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in

> reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

27. The False Claims Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

II. The Medicare Program

28. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, et seq. HHS is responsible for administering and supervising the Medicare program. CMS is the HHS component of that is directly responsible for administering the Medicare program.

29. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."

30. The Medicare program consists of four parts: A, B, C, and D. Part B covers outpatient care, including physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k. Part D provides prescription drug coverage. S*ee* 42 U.S.C. § 1395w-101, et seq.; 42 C.F.R. § 423.1, et seq. Part D prescription drug plans are administered by private insurance companies approved by the federal government and receive contributions from the federal treasury. 42 U.S.C. § 1395w-101, et seq.

A. The Medicare Part B Program

31. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C.

§ 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

32. The Secretary of HHS ("Secretary") is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). Typically, the Secretary acts through formal regulations and subregulatory guidance.

33. The Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet. *See generally*, CMS Internet-Only Manuals (IOMs), *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms.html (last visited May 31, 2019) (hereinafter "CMS Manuals").

34. At all times relevant to this complaint, CMS contracted with private contractors, referred to as Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.104. MACs generally act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level.

35. During the relevant time period of this Complaint, Palmetto GBA was the MAC responsible for processing Medicare Part B claims in South Carolina and North Carolina.

36. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

37. To participate in the Medicare program as a new enrollee, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855B. These entities must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.

38. Form CMS 855-B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited May 31, 2019).

39. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program." *Id.*

40. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

41. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was

personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.

42. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and NPI for the referring physician. 42 U.S.C. § 1395l(q)(1).

43. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. Among the information the provider or supplier includes on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source."

44. When submitting claims to Medicare, providers certify on the CMS 1500, *inter alia*, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to the CMS 1500, providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark Law)." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a

statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

45. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful." https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited May 31, 2019).

46. Health care providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

47. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

48. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

49. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

50. During the relevant time period, Defendants billed Medicare under Part B for medical services including, but not limited to, clinical laboratory services and steroid injections

furnished by physicians and other providers and suppliers, by submitting claims for reimbursement to Palmetto GBA.

B. The Medicare Part D Program

51. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. An individual is eligible to enroll in Part D if the individual lives in the service area of the Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

52. Unlike coverage in Medicare Part B, Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan "Sponsors" to administer prescription drug plans. A Part D Plan Sponsor may be either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan, a Program of All-inclusive Care for the Elderly ("PACE") organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

53. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. The Part D Sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into subcontracts with pharmacies or other downstream entities to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

54. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy (or submit it to a mail order specialty pharmacy) to be filled.

55. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D Plan Sponsor (sometimes through a pharmacy benefit manager ("PBM")) and receives reimbursement from the Part D Plan Sponsor (or the PBM) for the portion of the drug cost not paid by the Part D beneficiary.

56. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

57. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program. The data contained in PDEs are data related to payment of claims. The Integrated Data Repository process date is the date when the PDE is transmitted to CMS, such that CMS is informed of the PDE by the Part D Plan Sponsor.

58. Submitting PDE claims data to CMS, which is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors for qualified drug coverage, is a material condition of payment for CMS's provision of Medicare funds to Part D Plan Sponsors. *See* 42 C.F.R. § 423.322.

59. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to

cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

60. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor "in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus the monthly beneficiary premium as determined in 42 C.F.R § 423.286." 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

61. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies" and are documented and reconciled using PDE data submitted to CMS.

62. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. §§ 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for correcting submitted PDE data they determine are erroneous.

63. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records.

64. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws and regulations, as well as CMS instructions. By statute, all contracts between a Part D

Plan Sponsor and HHS must include a provision whereby the Part D Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program, as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112. Further, CMS regulations expressly require Part D Plan Sponsors to certify, in their contracts with CMS, that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the False Claims Act and AKS. *See* 42 C.F.R. § 423.505(h)(1).

65. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities, including pharmacies, contain language obligating the dispensing pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

66. Medicare Part D only pays for drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

67. Medicare Part D only pays for drugs that are dispensed upon a valid prescription. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.100. A "Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A valid prescription must comply "with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

68. Moreover, prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as recreational use, are not for "medically accepted indications"

and are therefore not covered Medicare Part D drugs. 42 USCA § 1395w-102(e)(1); 42 C.F.R. § 423.100.

69. All prescriptions for controlled substances are required to be dated as of, and signed on, the day when issued and to bear the full name and address of the patient; the drug name; strength; dosage form; quantity prescribed; directions for use; and the name, address, and registration number of the practitioner. 21 C.F.R. § 1306.05(a).

70. Part D plans may also exclude drugs from payment if the drugs are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body part. 42 U.S.C. § 1395w-102(e)(3) (incorporating by reference 42 U.S.C. § 1395y(a)).

71. During the relevant time period, Oaktree physicians wrote prescriptions for opioid medications and lidocaine ointment for Part D beneficiaries that were filled by pharmacies and paid for by Medicare.

III. South Carolina Medicaid Program

72. The South Carolina Medicaid Program is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 et seq. Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. The South Carolina Medicaid program is required to implement a "State Plan" containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. § 1396a.

73. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on a state's per capita income compared to the national

average. 42 U.S.C. § 1396d (b). During the relevant time period, the federal portion of South Carolina Medicaid payments ranged from 70.04% in 2011 to 71.58% in 2018:

Year	Federal Medical Assistance Percentage to South Carolina Medicaid
2011	70.04%
2012	70.24%
2013	70.43%
2014	70.57%
2015	70.64%
2016	71.08%
2017	71.3%
2018	71.58%

See Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier, Henry J. Kaiser Family Foundation, https://www.kff.org/medicaid/state-indicator/federal-matching-rate-and-multiplier (last visited May 31, 2019).

74. Pursuant to 42 C.F.R. § 431.18, the South Carolina Department of Health and Human Services ("SCDHHS") has issued South Carolina Medicaid Provider Manuals for the purpose of furnishing Medicaid providers with the policies and procedures needed to receive reimbursement for covered services provided to eligible South Carolina Medicaid recipients. Throughout the relevant time period, the South Carolina Medicaid Provider Manuals were available for review at the State office and in each local and district office, as well as online at www.scdhhs.gov.

75. In order to participate in the South Carolina Medicaid program, physicians and laboratories must certify in their state Medicaid participation and payment agreement forms that

"all services rendered, and claims submitted shall be in compliance with all applicable federal and state laws and regulations and in accordance with the South Carolina Plan for Medical Assistance, bulletins, SCDHHS policies, procedures, and Medicaid Provider Manuals."

76. The Physicians, Laboratories, and Other Medical Professionals Provider Manual for the South Carolina Medicaid program provides, in pertinent part:

> Medicaid will pay for a service when the service is covered under the South Carolina State Plan and is medically necessary. "Medically necessary" means that the service (the provision of which may be limited by specific manual provisions, bulletins, and other directives) is directed toward the maintenance, improvement, or protection of health or toward the diagnosis and treatment of illness or disability. A provider's medical records or other appropriate documentation for each beneficiary must substantiate the need for services, must include all findings and information supporting medical necessity and justification for services, and must detail all treatment provided.

77. State regulations promulgating the South Carolina Medicaid program rules, in defining medical necessity, specify "[t]he fact that a physician prescribed a service or supply does not deem it medically necessary." S.C. Code Ann. Regs. § 126–425.

78. In addition, an individual, clinic, or laboratory enrolled as a South Carolina Medicaid provider must submit claims on a CMS 1500, which contains the certifications specified above in Paragraph 44.

79. Because it is not feasible for the Medicaid program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with Medicaid requirements and relies on providers to submit truthful and accurate certifications and claims.

80. South Carolina Medicaid provides reimbursement for prescription medications. Under South Carolina law, a prescription for a controlled substance that was not issued for a legitimate medical purpose is not valid. S.C. Code Ann. § 44-53-360(h). Further, "[a]n order

purporting to be a prescription issued to a drug dependent person, not in the course of generally accepted medical treatment, but for the purpose of providing the user with controlled substances sufficient to maintain his dependence upon the substance, or to provide him with quantities of controlled substances in great excess of normal dosage ranges as recommended by the manufacturer of the substance" is not a valid prescription. *Id.*

IV. The TRICARE Program

81. TRICARE is a medical benefits program established by federal law. 10 U.S.C. §§ 1071-1110b. TRICARE covers eligible beneficiaries, which, *inter alia*, include active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. The federal government reimburses a portion of the cost of health care services and prescription medications provided to TRICARE beneficiaries. TRICARE is administered by the DHA.

82. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments. *See* 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at 32 C.F.R. § 199.2.

83. TRICARE regulations also provide that TRICARE may deny payment in "abuse situations." 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to provide

services and supplies under TRICARE that are: "Furnished at the appropriate level and only when and to the extent medically necessary . . .; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id.*

84. The TRICARE regulations, in turn, define "appropriate" medical care as that which is, *inter alia*, "[f]urnished economically"—i.e., "in the least expensive level of care or medical environment adequate to provide the required medical care." 32 C.F.R. § 199.2.

85. TRICARE requires a referral and/or prescription from the beneficiary's physician for laboratory tests.

86. TRICARE also offers its beneficiaries a prescription drug benefit. TRICARE beneficiaries may receive prescription drugs from three different sources: military treatment facilities, the TRICARE Mail Order Pharmacy, and retail pharmacies.

87. TRICARE will only pay "for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. . . . However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means." 32 C.F.R. § 199.4.

88. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

89. As with Medicare, providers submit claims to TRICARE using the CMS 1500 or an electronic equivalent. Providers therefore make the same certifications in submitting claims to TRICARE as they do when submitting claims to Medicare.

90. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and relies on providers to submit truthful and accurate certifications and claims.

V. Self-Referral and Anti-Kickback Prohibitions

A. The Stark Law

91. The Stark Law prohibits an entity from submitting claims to Medicare for certain categories of "designated health services" ("DHS"), including clinical laboratory services, if such services were referred to the entity by a physician with whom the entity had a financial relationship that did not comply with a statutory or regulatory exception. 42 U.S.C. § 1395nn(a)(1). The Stark Law further prohibits Medicare from paying any claims that do not comply with its terms. 42 U.S.C. § 1395nn(g)(1). The statute was designed specifically to prevent losses that might be suffered by the Medicare program due to overutilization of DHS, patient steering, stinting on care, and the corruption of physicians' medical judgment by improper financial incentives.

92. As initially enacted in 1989, the Stark Law applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992, by a physician to a laboratory with which the physician had a financial relationship unless a statutory or regulatory exception applied. *See* Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236-43. In 1993, Congress extended the Stark Law's application to

referrals for ten additional DHS. *See* Omnibus Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 312, 596-605; Social Security Act Amendments of 1994, Pub. L. No. 103-432, § 152, 108 Stat. 4398, 4436-37. In 2008, Congress added outpatient speech-language pathology services to the list of DHS. *See* Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 143, 122 Stat. 2494, 2542-43.

93. Compliance with the Stark Law is a condition of payment by the Medicare program. Medicare may not pay for any DHS provided in violation of the Stark Law. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1).

94. The regulations implementing the Stark Law require that "[a]n entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis[.]" 42 U.S.C. § 411.353(d).

95. In pertinent part, the Stark Law provides:

> (a) Prohibition of certain referrals
>
> (1) In general
>
> Except as provided in subsection (b), if a physician . . . has a financial relationship with an entity specified in paragraph (2), then
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
>
> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1).

96. As noted above, DHS includes clinical laboratory services. *See* 42 U.S.C. § 1395nn(h)(6) and 42 C.F.R. § 411.351.

97. Under the Stark Law, an "entity is considered to be furnishing DHS if it . . . [i]s the person or entity that has performed services that are billed as DHS or . . . that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned. . . ." 42 C.F.R. § 411.351.

98. A "financial relationship" includes a "compensation arrangement," which means any arrangement involving any "remuneration" paid to a referring physician "directly or indirectly, overtly or covertly, in cash or in kind" by the entity furnishing the DHS. *See* 42 U.S.C. §§ 1395nn(h)(1)(A), (h)(1)(B); 42 C.F.R. § 411.351.

99. A direct compensation arrangement exists "if remuneration passes between the referring physician . . . and the entity furnishing DHS without any intervening persons or entities." 42 C.F.R. § 411.354(c)(1)(i).

100. An indirect compensation arrangement exists if (i) there is an unbroken chain of persons or entities that have financial relationships between the referring physician and the entity furnishing DHS; (ii) the referring physician receives from the person or entity with whom the physician has a direct financial relationship aggregate compensation that varies with, or otherwise takes into account, the volume or value of the physicians' referrals to, or other business generated by the referring physician for, the entity furnishing the DHS; and (iii) the entity furnishing the DHS has knowledge of the remuneration being provided to the referring physician. *See* 42 C.F.R. § 411.354(c)(2).

101. A "referral" includes any request by a physician for, or ordering of, or the certifying or recertifying of the need for, any DHS for which Medicare payment may be made, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but does not include

any DHS personally performed by the referring physician. 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351.

102. "Other business generated" means "any other business generated by the referring physician, including other Federal and private pay business." 66 Fed. Reg. 856-01, 877 (January 4, 2001).

103. Compensation is "deemed not to take into account 'other business generated between the parties,' provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay healthcare business. . . ." 42 C.F.R. § 411.354(d)(3).

104. The Stark Law and its companion regulations set forth exceptions for certain financial relationships that meet specific enumerated requirements. The Stark Law's exceptions operate as affirmative defenses to alleged violations of the statute. Once it has been shown that a party submitting Medicare claims has a financial relationship with a referring physician, the defendant bears the burden of demonstrating that the relationship meets all of the requirements of an applicable statutory or regulatory exception. *See, e.g.*, *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 405 (4th Cir. 2012).

105. The Stark Law and its implementing regulations contain exceptions for certain compensation arrangements. These exceptions include, among others, exceptions for "in-office ancillary services" ("IOAS"), "*bona fide* employment relationships," "personal service arrangements," and "indirect compensation arrangements."

106. The IOAS exception allows a physician in a "group practice" (as defined at 42 C.F.R. § 411.352) to refer Medicare beneficiaries to his or her own group practice for the

furnishing of DHS if certain requirements are satisfied regarding the location, performance, and billing of the DHS. 42 U.S.C. §§ 1395nn(b)(2), (h)(4); 42 C.F.R. § 411.355(b).

107. The IOAS exception does not apply to DHS furnished by a physician group that is not a "group practice" as defined by the Stark Law. In order to qualify as a "group practice" under the Stark Law, the physician group must, *inter alia*, be organized as a "single legal entity" and no physician who is a member of the group can be compensated directly or indirectly based on the volume or value of his or her DHS referrals, except for certain productivity bonuses and profit shares that are not directly related to the volume or value of DHS referrals. *See* 42 U.S.C. § 1395nn(h)(4); 42 C.F.R. § 411.352(a), (g), (i).

108. To qualify for the Stark Law's exception for *bona fide* employment relationships, a compensation arrangement must meet, *inter alia*, the following requirements: the amount of remuneration under the employment (A) is consistent with the fair market value of the services, (B) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and (C) is commercially reasonable even if no referrals were made to the employer. *See* 42 U.S.C. § 1395nn(e); *see also* 42 C.F.R. § 411.357(c).

109. To qualify for the Stark Law's exception for personal service arrangements, a compensation arrangement must meet, *inter alia*, the following statutory requirements: the compensation (A) is set in advance, (B) does not exceed fair market value, and (C) is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties (except for compensation received pursuant to a "physician incentive plan" as defined by the Stark Law). *See* 42 U.S.C. § 1395nn(e)(3)(A); *see also* 42 C.F.R. § 411.357(d). A "physician incentive plan" under § 1395nn(e)(3) is narrowly

defined and only applies to personal service arrangements that "may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity." 42 U.S.C. § 1395nn(e)(3)(B)(ii).

110. To qualify for the Stark Law's exception for indirect compensation arrangements, the following requirements, *inter alia*, must be satisfied: (A) the compensation received by the referring physician is fair market value for items and services actually provided by the physician, (B) the physician's compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity, (C) the compensation is for identifiable services, and the arrangement is commercially reasonable even in the absence of referrals to the entity, and (D) the arrangement does not violate the AKS. *See* 42 C.F.R. § 411.357(p).

111. The Stark Law is a strict liability statute, with no scienter component. Medicare providers who knowingly submit claims to the Medicare program in violation of the Stark Law may be found liable for violation of the False Claims Act. *See, e.g., United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015). A knowing violation of the Stark Law may also subject the billing entity to exclusion from participation in federal health care programs and civil monetary penalties. 42 U.S.C. §§ 1395nn(g)(3), 1320a-7a(a).

B. The Anti-Kickback Statute

112. The AKS arose out of Congressional concern that providing things of value to those who can influence health care decisions may corrupt their professional judgment and result in federal funds being diverted to pay for goods and services that are medically unnecessary, of poor quality, or even harmful to patients.

113. The AKS prohibits the payment of kickbacks in order to protect the integrity of Medicare, TRICARE, and other federal health care programs, including Medicaid. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b)-(c), 86 Stat. 1329, 1419-20; 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977); Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat 680.

114. The AKS prohibits any person or entity from soliciting, receiving, offering, or paying any remuneration as an inducement or reward for referring, recommending, ordering, or arranging for the purchase of any item or service for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> b. Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.

42 U.S.C. § 1320a-7b(b).

115. Subject to specified exceptions, the AKS prohibits offering or paying any remuneration that has, as one purpose, inducement of a provider's referrals to federal health care programs. Claims that include items or services resulting from a violation of the AKS are false or fraudulent under the FCA. 42 U.S.C. §1320a-7b(g); *see also, e.g., United States ex rel. Lutz v. Berkeley Heartlab, Inc*., 225 F. Supp. 3d 487, 498 n.2 (D.S.C. 2016) ("[T]his Court finds that the weight of authority supports the conclusion that the 2010 amendment adding 42 U.S.C. 1320a-7b(g) was merely a clarification of the law; claims tainted by AKS violations constitute false claims for the purposes of the FCA regardless of whether the violation occurred before or after the 2010 amendment.") (appeal pending post-judgment).

116. The Office of Inspector General for the Department of Health and Human Services ("HHS-OIG") has published safe harbor regulations defining arrangements that are not prohibited by the AKS because the practice would be unlikely to result in fraud or abuse. Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor and is an affirmative defense to an alleged AKS violation.

117. There is a statutory exception and corresponding safe harbor to the AKS for payments by an employer to its *bona fide* employees. 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i). According to the safe harbor regulation, the term "employee has the same meaning" as the Internal Revenue Code's definition of "employee," found in 26 U.S.C. § 3121(d)(2). 42 C.F.R. § 1001.952(i). The Internal Revenue Code provides, in relevant part, that

an "employee" is "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee." 26 U.S.C. § 3121(d)(2).

VI. Urine Drug Testing Overview

A. Regulatory Requirements for Laboratory Test Services

118. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

119. "Clinical laboratory services involve the . . . examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02, Ch. 15, § 80.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (last visited May 31, 2019).

120. Medicare regulations make clear that (1) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (2) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are not covered services; and (3) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. *See* 42 C.F.R. § 410.32.

121. In particular, pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the

management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." The MPBM's "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary . . . . [T]he physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, § 80.6.1.

122. Clinical laboratory services must also be used promptly by the physician who is treating the beneficiary as described in 42 C.F.R. § 410.32(a). *See* MPBM, Ch. 15, § 80.1.

123. In order to assess whether those services are reasonable and necessary and whether reimbursement is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e); *see also* 42 U.S.C. § 1395u(c)(2)(B)(i) ("The term 'clean claim' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) . . . .").

124. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

125. Medicare regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> ***(iii) Medical necessity.*** The entity submitting the claim may request additional diagnostic and other medical information from the ordering

> physician or nonphysician practitioner to document that the services it bills are reasonable and necessary.

42 C.F.R. § 410.32(d)(3).

126. The South Carolina Medicaid program imposes similar requirements. As noted above in connection with the Physicians, Laboratories, and Other Medical Professionals Provider Manual for the South Carolina Medicaid program, services must be individualized to the medical needs of each patient; moreover, providers must maintain appropriate documentation for each beneficiary, substantiating the need for services, including all findings and information supporting medical necessity, and detailing all treatment provided.

127. In addition, for laboratory services or tests to be covered by South Carolina Medicaid, those services must be ordered by a professional practitioner within the scope of his or her practice with the expectation of making a reasonable medical determination. S.C. Code Ann. Regs. § 126-311.

128. Similarly, TRICARE only pays for laboratory tests that are "medically or psychologically necessary" and "required in the diagnosis and treatment of illness or injury." 32 CFR § 199.4(a)(1). TRICARE will not cover tests that are "not related to a specific illness or injury or a definitive set of symptoms." *Id*. at (g)(2).

129. As noted above, TRICARE regulations provide that TRICARE may deny payment in "abuse situations." 32 CFR 199.9(b). The regulations expressly include as examples of "abuse or possible abuse situations" the following: (i) "a battery of diagnostic tests are given when, based on the diagnosis, fewer tests were needed," and (ii) "[f]ailure to maintain adequate medical or financial records." *Id.*

130. Laboratories have a "'legal duty to ensure that [they are] not submitting false or incorrect claims to Government . . . payors.'" *United States ex rel. Groat v. Boston Heart*

Diagnostics Corp., 296 F. Supp. 3d 155, 165 (D.D.C. 2017) (quoting Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076, 45,077 (Aug. 24, 1998)). As part of that duty, "laboratories should ensure that they do not submit claims for medically unnecessary tests by, *inter alia*, communicating with physicians regarding medical necessity, maintaining documentation of medical necessity, constructing requisition forms to promote conscious ordering of tests by physicians, and reviewing coding." *Id*. (citing 63 Fed. Reg. at 45,079-80). Courts have held laboratories liable under the FCA where they engage in schemes "to encourage . . . physicians to order medically unnecessary tests." *United States ex rel. Lutz v. Lab. Corp. of Am. Holdings*, No. 9:14-CV-3699-RMG, 2019 WL 236799, at *3 (D.S.C. Jan. 16, 2019) (quoting *Groat*, 296 F. Supp. 3d at 165).

B. Types of Urine Drug Tests

131. Drug testing is used to determine the presence or absence of drugs or metabolites. Drug testing can be "qualitative" (to determine the presence or absence of a drug or metabolite) or "quantitative" (to provide a numerical concentration of a drug or metabolite). Different testing methodologies have different capabilities and limitations.

132. Drug testing is performed in a number of contexts. In the clinical health care context, drug testing can be used to monitor whether patients are taking prescribed drugs, or taking or abusing drugs not prescribed.

133. Urine is the most common medium used for drug testing and is the medium for testing that has been utilized during the relevant time period by Oaktree, Labsource, and ProLab.

134. Urine drug testing ("UDT") is done in two stages: presumptive testing (sometimes referred to as "screening" testing) and, when necessary, definitive testing (sometimes referred to as "confirmatory" testing). First, the treating provider performs a presumptive test.

The presumptive test gives a positive result when the presence of a drug or metabolite in the urine exceeds a given concentration and a negative result when the drug or metabolite is below this concentration.

135. There are two primary methods of performing presumptive tests. These tests can be performed using a point of care ("POC") testing cup or test strips that are dipped into a urine sample. POC testing cups and test strips are relatively inexpensive and typically feature a panel of 11 or 12 treated strips, one for each drug or drug class being tested. When the strips are dipped into the urine specimen, a change in color signifies the presence or absence of the specific drug or drug class for which each strip tests. Using POC cups or strips, a provider can receive almost immediate results for the substances tested in his or her own office. Alternatively, presumptive tests can be performed by an immunoassay analyzer, a device found in laboratories and in some physicians' offices that rapidly determines the presence or absence of the tested drugs and are generally reimbursed at higher levels than POC test cups and strips.

136. Under CLIA, CMS oversees all laboratory testing services. UDT performed using POC test cups and test strips is generally "CLIA-waived." CLIA-waived tests are categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result or pose no risk of harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 42 C.F.R. § 493.35. To operate an immunoassay analyzer, physician practices and laboratories are generally required to obtain a CLIA certification to perform moderate or high complexity laboratory tests. 42 C.F.R. §§ 493.20, 493.25.

137. Presumptive tests utilizing POC test cups and strips and immunoassay analyzers represent the standard of practice for drug testing in pain management. As detailed below, most

patients need only limited, if any, definitive UDT performed at a laboratory based on their presumptive test results, drug abuse history, and clinical presentation.

138. Definitive UDT is conducted in laboratories that can perform mass spectrometry and either gas or liquid chromatography. These testing methodologies can provide quantitative results, identifying the concentration of a drug or metabolite in a sample. The equipment required to perform definitive UDT is more sophisticated, and most treating providers are not equipped to perform definitive testing themselves. Instead, treating providers typically refer definitive drug testing to independent laboratories, such as Labsource or one of its competitors. It usually takes a couple of days to receive results back from definitive testing.

139. The clinical value of definitive UDT depends in part on whether the presumptive test result is expected or unexpected, as well as the patient's history of drug abuse, history of medication adherence and compliance, clinical presentation, and/or medical history. For example, if a patient is prescribed a certain drug, such as Xanax, a positive presumptive test result for benzodiazepines (of which Xanax is one) would be expected. If the test result is negative for benzodiazepines, however, and the patient insists that she is taking her Xanax as prescribed, a definitive laboratory test to "confirm" this unexpected negative result may be reasonable and necessary.

140. Similarly, if a patient's presumptive test yielded a positive result for a non-prescribed or illicit drug, then definitive UDT to evaluate this unexpected positive result may, under certain circumstances and depending on individual patient factors, be reasonable and necessary.

141. In some unusual circumstances, definitive UDT of an expected presumptive test result or for a substance not available on a presumptive test may also be medically reasonable

and necessary. For example, aberrant patient behavior, a patient's unexpected clinical presentation, and/or a patient's particular history of drug abuse may justify specific definitive UDT. The reasonableness and necessity of such tests, however, depends on the presentation and provider assessment of each individual patient and that patient's individual circumstances. If a presumptive test is negative for an illicit drug or a drug not prescribed, and there is nothing in the patient's presentation or drug abuse history to indicate abuse of that drug, then routine definitive UDT for that drug is not reasonable and necessary for the treatment and diagnosis of that patient, and therefore not covered by federal health care programs, including Medicare, Medicaid, and TRICARE.

142. In all situations, definitive UDT should be utilized only to the limited extent it is necessary for an individual patient, based on that individual's presumptive test results and other factors specific to that individual. Widespread definitive UDT should not be ordered as a matter of course.

143. Local Coverage Determinations ("LCDs") are determinations issued by MACs "respecting whether or not a particular item or service is covered" by the MAC. 42 U.S.C. § 1395ff(f)(2)(B). At various points during the relevant time period, Palmetto GBA issued LCDs regarding UDT. These LCDs were made available to all providers within Palmetto GBA's jurisdiction. In general, these LCDs provided guidance regarding the appropriate indications for and expected frequency of presumptive and definitive UDT. As part of that guidance, the LCDs indicated that the use of routine standing orders is not reasonable and necessary.

144. For example, on October 1, 2015, Local Coverage Determination ("LCD") L35724, took effect in Medicare Jurisdiction M, which includes South Carolina and North Carolina. L35724 provided coverage guidance regarding presumptive and definitive UDT and

required that the following elements, at a minimum, be used to determine medical necessity: (1) the patient's history, physical examination, and previous laboratory findings; (2) the patient's current treatment plan; (3) the patient's prescribed medication(s); and (4) and the patient's risk assessment plan. This LCD indicated that it was not reasonable and necessary for a physician to perform presumptive POC testing or presumptive immunoassay testing and order presumptive immunoassay testing from a reference laboratory. This LCD also stated that definitive UDT orders "should be individualized based on clinical history and risk assessment, and must be documented in the medical record." The LCD also indicated that the use of routine standing orders for all patients in a provider's practice is not reasonable and necessary.

145. Defendants had knowledge of these LCDs but nevertheless continued to refer orders for, or perform, unreasonable and unnecessary UDT that was billed to Medicare, Medicaid, and TRICARE, as described below.

C. Reimbursements for Laboratory Tests

146. Different types of urine drug tests have different costs.

147. During the relevant time period, Medicare generally reimbursed presumptive UDT based on the methodology (analyzer versus POC test cup or strip) used by the physician practice or the complexity of the test under CLIA. During the relevant time period, POC tests were reimbursed by Medicare at a rate of $12-25 and high-complexity analyzer tests were reimbursed by Medicare at a rate of $65-$100.

148. Prior to January 1, 2016, definitive UDT was generally billed using individual CPT codes for each and every drug or drug class tested. In response to concerns regarding the potential for overpayment when billing for each individual drug test, CMS revised the way that it reimbursed definitive UDT under the Medicare program, effective January 1, 2016. *See*

Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads /Archive-Test-Codes-and-Payment-Determinations-files-.zip (last viewed May 31, 2019). In particular, rather than continuing to permit providers to bill for each and every individual definitive drug test, CMS created four CPT codes for definitive UDT: G0480, G0481, G0482, and G0483. Only one of these four definitive UDT codes may be billed per patient per day. *Id*. The following table defines these codes and their corresponding 2016 Medicare reimbursement amount:

Definitive UDT Code	Definition	2016 Medicare Reimbursement
G0480	Definitive drug testing for 1-7 drug classes, including metabolites.	$79.94
G0481	Definitive drug testing for 8-14 drug classes, including metabolites.	$122.99
G0482	Definitive drug testing for 15-21 drug classes, including metabolites.	$166.03
G0483	Definitive drug testing for 22 or more drug classes, including metabolites.	$215.23

See id.; 2016 Clinical Diagnostic Laboratory Fee Schedule, *available at* https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/16CLAB.zip (last visited May 31, 2019).

149. In order to prevent abuse, South Carolina Medicaid issued a Medicaid Bulletin to providers making effective on January 1, 2016, the limitation that SCDHHS will reimburse a maximum of one presumptive test per procedure code per date of service, not to exceed 18 presumptive tests per 12-month period. *See* Coverage of Drug Testing Codes, Medicaid Bulletin

16-016 (July 21, 2016). Since September 1, 2016, South Carolina Medicaid only reimburses the G0480 code for definitive UDT at a rate of $63.95.

150. During the relevant time period, TRICARE followed Medicare's reimbursement methodology for UDT.

VII. Injection Procedures Overview

151. The treatment and diagnosis of chronic pain may at times require interventional procedures involving injections into muscles and tendons, or into joints such as the spine (facet joints), knees, hips, elbows, or shoulders.

152. A medical provider with proper training can administer these injections to diagnose or treat pain by using an anesthetic to block nerve signals, sometimes called a nerve block, or by decreasing inflammation through use of a steroid in the injection. Many times these interventions involve using a combination of both approaches.

153. Facet joints are joints in the spine that aid stability and allow the spine to bend and twist. Facet joint injections are a type of interventional pain management technique used to diagnose or treat axial back pain, which is a band-like pain in the back or neck. Physicians typically perform facet joint injections using radiological guidance to ensure correct needle placement and avoid nerve or other injury.

154. Determining whether a patient is a candidate for an injection, and, if a candidate, the type of injection clinically appropriate, depends on the patient's clinical presentation after a musculoskeletal and neurological physical examination, combined at times with a review of diagnostic imaging such as an x-ray.

155. The clinical presentation of a patient is key to determining the mode and method of an interventional procedure. An abnormal diagnostic image alone is not determinative of

necessity for interventional pain procedure. The majority of asymptomatic older adults have degenerative changes seen in imaging of the spine. Furthermore, even in patients who have pain, the pain may be coming from only one of numerous radiographically abnormal structures in the spine, and it may not be a structure amenable to treatment by injection. Since these injection procedures only serve to alleviate symptoms, they are not reasonable and necessary in patients without symptoms or in patients with symptoms caused by an anatomic structure other than the target of the treatment with an injection.

156. Drugs used in facet and other joint injections may cause adverse events. For instance, the frequent injection of steroids into a joint or muscle could lead to weakening or necrosis of the area injected, nerve damage, or infection.

157. Accordingly, a clinical assessment must implicate the specific facet joint whose therapeutic target is the injection as the putative source of pain, and pre-procedural documentation must include a complete initial evaluation including an appropriately focused musculoskeletal and neurological physical examination.

158. Among other requirements for Medicare payment, a patient must have a history of at least 3 months of moderate to severe pain with functional impairment that has not been adequately responsive to more conservative care.

DEFENDANTS' FRAUDULENT SCHEMES

159. As detailed below, McCollum and his businesses used a variety of schemes to provide kickbacks and create unlawful financial incentives for providers to make referrals of UDT to his laboratories; to routinely order excessive UDT for all patients (including Medicare, Medicaid, and TRICARE beneficiaries), regardless of individual patient assessment or need; and

to routinely provide medically unnecessary opioid and lidocaine prescriptions and pain injections to patients (including Medicare, Medicaid, and TRICARE beneficiaries).

I. Stark Law Violations

160. As discussed above, McCollum owned and operated numerous pain management clinics throughout the Carolinas (e.g., Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina) that collectively did business as PMA. Even though physicians working at the various PMA clinics had employment agreements with the specific clinic, they were actually employed and paid by Oaktree and, hereinafter, will be referred to as "Oaktree physicians."

161. In addition to providing clinical services to patients, Oaktree also performed and billed for clinical laboratory services, such as presumptive and definitive UDT, that were ordered and referred by Oaktree physicians working at the various PMA clinics. Patients were seen for an office visit by an Oaktree physician at one of the PMA clinics and provided a urine sample for testing. For at least a portion of the relevant time period, the physician performed a presumptive POC test at the PMA clinic and ordered definitive UDT that was sent to and processed by Oaktree. Oaktree performed a presumptive immunoassay test and definitive UDT on the urine samples sent by the PMA clinic, and then billed the patient's insurer for this testing.

162. In or around mid-2013, McCollum began operating an independent clinical laboratory, Labsource. Around this time and through December 31, 2018, PMA clinics also sent patient urine samples to Labsource for presumptive and definitive UDT.

163. During the relevant time period, McCollum, Oaktree, and Labsource engaged in a scheme to compensate Oaktree physicians by directly taking into account the volume or value of DHS referrals to and other business generated (e.g., private pay and non-Medicare referrals) by

those physicians for Oaktree and Labsource. As discussed below, the direct and indirect compensation arrangements with the Oaktree physicians did not satisfy the requirements of any applicable exception to the Stark Law. Nonetheless, Oaktree and Labsource submitted claims to Medicare for services resulting from those referrals, in violation of the Stark Law.

A. Oaktree Paid Physicians for Referrals of DHS to Oaktree in Violation of the Stark Law.

164. During most of the relevant time period of this Complaint (January 1, 2011 through at least December 31, 2018), Oaktree employed physicians pursuant to written employment agreements ("contracts") signed by each physician and by the practice owner, Daniel McCollum, or by Michael Brohm, who succeeded McCollum as PMA's CEO in or around April 2015. In exchange for the compensation set forth in each contract, each physician agreed to render medical services for Oaktree and its affiliated PMA clinics and assigned to Oaktree and its affiliated PMA clinics the right to bill for such services.

165. Although each physician contract contained different payment provisions and changed over time, they all generally provided that the physician would be paid a fixed base salary, or a percentage of the physician's gross collections, whichever was greater. If the physician's gross collections exceeded the physician's fixed base salary, Oaktree paid the physician the difference as a bonus.

166. Many physician contracts defined gross collections to include "revenue from ancillary services," "revenue that is generated from ancillary services such as NCV/EMG, urine drug screen, and MRI," or "any in-house laboratory testing or diagnostic imaging for patients under Employee's care or referral."

167. Physicians who, at various times during the relevant time period (as specified below), had employment agreements with compensation terms substantially similar to those described above include, but are not limited to the following:

Physician	Approximate Dates Physician Contracts Contained Substantially Similar Compensation Terms During Relevant Time Period (1/1/2011 to 12/31/2018)
Richard Banks, M.D.	1/1/2011 to 11/1/2013
Robert Blackwell, M.D.	1/1/2011 to 6/4/2013
Thomas Fox, M.D.	1/1/2011 to 12/31/2016
Dwight Jacobus, D.O.	1/1/2011 to 12/31/2016
Regina Morris-Solis, M.D.	5/15/2013 to 12/18/2015
Sybil Reddick, M.D.	1/1/2011 to 02/12/2016
David Rogers, M.D.	1/1/2011 to 06/1/2017
Lesco Rogers, M.D.	10/6/2014 to 10/26/2015
Ryan Rosen, M.D.	7/18/2011 to 09/1/2013
Daniel Sheehan, M.D	12/16/2013 to 1/1/2015
Danny Smith, M.D.	1/1/2015 to 1/12/2016
Stephanie Vanterpool, M.D.	7/7/2014 to 11/30/2015
Robert Westrol, M.D.	1/1/2011 to 12/31/2017
Brian Wiley, M.D.	11/19/2014 to 12/31/2016

168. At various times during the relevant time period, some physicians, including but not limited to Regina Morris-Solis, M.D., Jay Patel, M.D., and Christopher Rubel, M.D., had employment contracts that purportedly excluded DHS collections from the physician's bonus computation, purportedly were based only on the physician's personally performed services, or otherwise purported to comply with the Stark Law. However, McCollum and Oaktree maintained spreadsheets indicating that these physicians' compensation was calculated in a manner that varied with and took into account the volume or value of the physician's DHS referrals to or other business generated for Oaktree and Labsource.

169. In or around 2017, after learning of the United States' investigation into these practices, Oaktree physician contracts were revised to provide that the physicians would be paid the greater of a fixed yearly salary or compensation calculated according to a formula that included the following amounts:

> a. Thirty-Five Percent (35.0%) of gross collections from clinical services, plus (ii) Twenty Percent (20.0%) of gross collections from laboratory services, plus (iii) Thirty-Percent (30.0%) of gross collections from pharmacy services, plus (iv) Fifteen percent (15.0%) of gross collections from NCV and EMG interpretations, the sum of which is referred to as Qualifying Gross Collections;
>
> b. If Employee supervises one or more mid level providers (physician assistant and/or advanced nurse practitioner), then Employee will be paid Five Percent (5.0%) of each mid level's Qualifying Gross Collections on a quarterly basis;
>
> . . .
>
> Gross collections includes cash collections, net of refunds, less drug and supply reimbursement received by Employer during the Employment for professional services personally performed by Employee, excluding collections received for "designated health services" as defined in 42 U.S.C. 1395nn and regulations promulgated thereunder.

170. While the 2017 revisions to the physician contracts purported to change the manner in which Oaktree compensated its employed physicians by, among other things, limiting the compensation to "professional services personally performed by Employee" and excluding "collections received for 'designated health services,'" in fact, McCollum and Oaktree continued compensating physicians by directly taking into account the volume or value of their Medicare UDT referrals to and other business generated (e.g., private pay and other non-Medicare UDT referrals) for Oaktree and Labsource, in violation of the Stark Law.

171. Physicians who entered into a revised employment agreement in 2017 or 2018, as described above, include but are not limited to:

Physician	Approximate Relevant Dates of Revised Compensation Term Contracts
Jeffrey Farricielli, M.D.	3/28/2018 to 12/31/2018
Gisele Girault, M.D.	3/31/2017 to 12/31/2018
Blake Leche, M.D.	5/20/2017 to 12/31/2018
Joseph O'Quinn, M.D.	2/6/2017 to 12/31/2018
Jay Patel, M.D.	5/8/2017 to 12/31/2018
David Rogers, M.D.	6/1/2017 to 12/31/2018
Christopher Rubel, M.D.	1/15/2018 to 03/04/2018
Elizabeth Snoderly, D.O.	3/13/2017 to 12/31/2018

172. Since the physicians were employed and paid by Oaktree, they had a direct compensation arrangement with Oaktree for purposes of the Stark Law.

173. During the relevant time period, Oaktree paid many of its employed physicians compensation that directly took into account the volume or value of their DHS referrals (and, specifically their UDT referrals) to Oaktree. Because of this fact, Oaktree could not qualify as a "group practice" under 42 C.F.R. § 411.352 and, therefore, the exception for in-office ancillary services at 42 C.F.R. § 411.355(b) was not applicable to the physicians' referrals for and Oaktree's billing of that UDT to Medicare. In addition, because of this fact, Oaktree failed to meet the requirements of the Stark Law's exception for *bona fide* employment relationships, 42 U.S.C. § 1395nn(e)(2), 42 C.F.R. § 411.357(c). Oaktree also failed to meet the Stark Law's exception for personal service arrangements, 42 U.S.C. § 1395nn(e)(3), 42 C.F.R. § 411.357(d), because the compensation it paid its physicians was determined in a manner that took into account the volume or value of their DHS referrals and other business generated (e.g., private pay and other non-Medicare referrals) between the physician and Oaktree.

174. Throughout the existence of these direct compensation arrangements, Oaktree's employed physicians made referrals of UDT to Oaktree in violation of the Stark Law, as a result

of which Oaktree submitted thousands of claims to Medicare that were false or fraudulent because they were ineligible for payment.

B. Oaktree Paid Physicians for Referrals of DHS to or Other Business Generated for Labsource in Violation of the Stark Law.

175. From mid-2013 to at least December 31, 2018, physicians employed by Oaktree had indirect compensation arrangements with Labsource because (i) there was an unbroken chain of entities in financial relationships (ownership or compensation) with each other: Physician --- (employment) --- Oaktree --- (ownership) --- McCollum --- (ownership) --- Labsource); (ii) under their employment arrangements with Oaktree, as set forth in Paragraphs 164–171, the physicians received aggregate compensation from Oaktree that varied with, or took into account, the volume or value of DHS referrals or other business generated by the referring physician for Labsource; and (iii) Labsource (through McCollum) had actual knowledge, or acted with reckless disregard or deliberate ignorance of the fact, that the physicians received such compensation. 42 C.F.R. § 411.354(c)(2).

176. Labsource's indirect compensation arrangements with the physicians failed to meet the requirements of the Stark Law exception for indirect compensation arrangements, 42 C.F.R. § 411.357(p), or any other applicable statutory or regulatory Stark Law exception because, at minimum, physicians received compensation that directly varied with and took into account the volume and value of their Medicare UDT referrals and other business generated (e.g., private pay and other non-Medicare UDT referrals) for Labsource.

177. Throughout the existence of these indirect compensation arrangements, Oaktree physicians made referrals of UDT to Labsource in violation of the Stark Law, as a result of which Labsource submitted claims to Medicare that were false or fraudulent because they were ineligible for payment.

C. Specific Examples of Oaktree Physicians' Compensation Arrangements that Violated the Stark Law

178. The following Paragraphs provide examples of physicians who had a direct compensation arrangement with Oaktree and an indirect compensation arrangement with Labsource:

i. Dr. Daniel Sheehan

179. Dr. Daniel Sheehan signed a one-year employment contract with Oaktree on December 5, 2013. The contract provided that Dr. Sheehan would

> be paid a monthly salary, less appropriate tax withholdings, equal to the greater of either (i) thirty-five percent (35%) of gross collections related to the patients seen by Employee during that month (including revenue generated from ancillary services), or (ii) One Thousand Dollars ($1000) per day. . . . Employee's entitlement to salary based on a percentage of gross collections as described above will be calculated using monthly billing collection reports generated on or around the last day of each month. If 35% of Employee's gross collections for said month are greater than the amount that Employee has received based on days worked, then Employer will pay Employee the difference. However, if 35% of Employee's gross collections for said month are less than the amount that Employee has received based on days worked, then he will not be entitled to payment based on 35% of his gross collections in any subsequent months until any and all prior deficiencies are made up.

180. Pursuant to Sheehan's contract, in 2014, Oaktree paid Dr. Sheehan approximately $362,007.82, which was comprised of $221,351.32 of regular pay and an aggregate bonus amount of $140,656.52. Moreover, in 2015, Oaktree paid Dr. Sheehan an additional $129,038.30 for "unpaid commission" from 2014. Dr. Daniel Sheehan's compensation from Oaktree was not limited to his personally performed services or to non-DHS; rather Dr. Sheehan received a percentage of *all* collections received by Oaktree and Labsource as a result of his referrals, all of which were DHS or other business generated (e.g., private pay and other non-Medicare referrals).

181. In 2014, Oaktree submitted at least 894 claims for UDT referred by Dr. Sheehan to Medicare, and received payments from Medicare for those claims totaling approximately $225,254. In the same year, Labsource submitted at least three claims for UDT referred by Dr. Sheehan, and received payments from Medicare for those claims totaling approximately $1,082. Each of these claims was false, and was accompanied by a false certification, because the referrals from Dr. Sheehan and the claim submissions were prohibited under the Stark Law. Oaktree and Labsource retained the payments they unlawfully received from Medicare for UDT referred by Dr. Sheehan, despite these Stark Law violations.

ii. Dr. Dwight Jacobus

182. In June 2010, Dr. Jacobus entered into an employment contract with Oaktree providing that Dr. Jacobus would be paid "$120,000 per year or 40% of his gross collections, whichever is greater. Gross collections means the amount of money actually collected from any sources as a result of Employee's services."

183. Dr. Jacobus also set up a limited liability company, Medical Management & Design Consultants, LLC ("MMDC"), that entered into a separate contract with Oaktree that provided that MMDC would be paid "$200,000 per year or 40% of gross collections, whichever is greater." Again, gross collections was defined in this contract to be "the amount of money actually collected from any source as a result of MMDC's services."

184. Per the MMDC contract, MMDC was to "provide 100% of the necessary marketing and design ads as related to pain management and orthopedic surgical services." However, according to Dr. Jacobus, MMDC was actually set up to compensate him for his role as a medical director for PMA. Dr. Jacobus also stated that he "didn't do much as a medical director except get called a medical director."

185. Moreover, spreadsheets maintained by McCollum and other PMA management-level employees indicate that at least a portion of Dr. Jacobus's salary and bonus payments derived from his clinical services, including UDT referrals, were paid to his MMDC account.

186. In 2012, Dr. Jacobus's compensation from Oaktree was all paid to his MMDC account. Oaktree paid Dr. Jacobus's MMDC a "stipend" of approximately $200,000 and a bonus payment of $183,770. In 2013, Oaktree paid Dr. Jacobus's MMDC a "stipend" of approximately $200,000 and a bonus payment of approximately $216,387. In 2014, Oaktree paid Dr. Jacobus a salary of approximately $120,000. Oaktree also paid Dr. Jacobus's MMDC a "stipend" of approximately $200,000 and a bonus payment of approximately $201,549. Similarly, in 2015, Dr. Jacobus received a salary of approximately $119,250 from Oaktree. Oaktree also paid Dr. Jacobus's MMDC a "stipend" of approximately $200,000. Dr. Jacobus also received a bonus payment of approximately $84,766 that was paid by Oaktree to MMDC. In 2016, Oaktree paid Dr. Jacobus a salary of approximately $119,250 and a bonus of approximately $10,147. Dr. Jacobus's compensation from Oaktree was not limited to his personally performed services or to non-DHS; rather Dr. Jacobus received a percentage of *all* collections received by Oaktree and Labsource as a result of his referrals, all of which were DHS or other business generated (e.g., private pay and other non-Medicare referrals).

187. Accordingly, Oaktree's agreement with MMDC was a sham and was, in fact, a scheme to circumvent the Stark Law's prohibition on paying physicians amounts directly tied to the volume or value of their DHS referrals.

188. From 2012 through 2016, Oaktree submitted approximately 8,921 claims for UDT that were referred by Dr. Jacobus to Medicare resulting in a payment from Medicare for those claims of approximately $2,473,290. Labsource submitted approximately 1,763 claims for UDT

that was referred by Dr. Jacobus, resulting in payment of Medicare for those claims of approximately $432,079. Each of these claims was false because the referrals from Dr. Jacobus and the claim submissions were prohibited under the Stark Law. Oaktree and Labsource retained the payments they unlawfully received from Medicare for UDT referred by Dr. Jacobus, despite the Stark Law violations.

iii. Other Oaktree Physicians

189. Since the Oaktree physician contract compensation terms required a physician's percent of gross collections to exceed his or her base salary, not all physicians earned a bonus. Nevertheless, the Oaktree physicians were incentivized to order excessive UDT because their compensation directly varied with and took into account the volume or value of their UDT referrals (Medicare and non-Medicare) for Oaktree and Labsource. In other words, the more UDT the physician referred to Oaktree or Labsource, the more the physician would be paid.

190. The following table provides some additional examples of physicians who, at various times throughout the relevant time period (as specified below), received compensation that varied with and took into account the volume or value of their DHS referrals to, or other business generated for, Oaktree and Labsource in violation of the Stark Law:

Physician	Approx. Dates Physician Eligible for Bonus Based on DHS Referrals or Other Business Generated	Estimated # of Medicare Claims for UDT Furnished By Oaktree	Estimated Medicare Payments to Oaktree for UDT	Estimated # of Medicare Claims for UDT Furnished By Labsource	Estimated Medicare Payments to Labsource for UDT
Robert Blackwell, M.D.	1/1/2011 to 6/5/2013	7,616	$2,489,182.39	0	$0
Dwight Jacobus, D.O.	1/1/2011 to 12/31/2016	9,833	$2,662,424.03	1763	$432,079.19
Blake Leche, M.D.	5/20/2017 to 12/31/2018	0	$0	54	$16,862.84
Regina Morris-Solis, M.D.	5/15/2013 to 12/31/2017	1,070	$289,905.06	1296	$350,784.26
Jay Patel, M.D.	1/1/2011 to 12/31/2018	3,317	$885,271.87	1180	$323,126.35
Sybil Reddick, M.D.	1/1/2011 to 2/12/2016	7,631	$2,090,483.17	673	$196,818.79
David Rogers, M.D.	1/1/2011 to 12/31/2018	4,938	$1,267,639.70	2072	$562,137.91

Lesco Rogers, M.D.	10/6/2014 to 12/31/2015	8	$3,247.66	640	$181,940.42
Ryan Rosen, M.D.	7/18/2011 to 09/01/2013	1,452	$424,155.79	0	0
Christopher Rubel, M.D.	3/9/2012 to 3/4/2018	11,123	$2,687,887.76	3478	$944,597.38
Daniel Sheehan, M.D.	12/16/2013 to 1/1/2015	894	$225,254.80	4	$1,082.48
Elizabeth Snoderly, D.O.	3/13/2017 to 12/31/2018	0	0	211	$61,841.54
Stephanie Vanterpool, M.D.	7/7/2014 to 11/30/2015	346	$101,600.81	214	$60,836.84
Robert Westrol, M.D.	1/1/2011 to 12/31/2017	1,680	$440,711.43	401	$94,072.57
Brian Wiley, M.D.	11/19/2014 to 12/31/2016	280	$88,498.03	872	$214,148.01

D. McCollum, Oaktree, PMA, and Labsource Knowingly Submitted or Caused the Submission of Claims to Medicare in Violation of the Stark Law

191. At all relevant times, McCollum, Oaktree, PMA, and Labsource were aware of the compensation terms and formulas included in the physician employment agreements, as described in Paragraphs 164-171, above. The fact that certain agreements purported to exclude

DHS or explicitly mentioned the Stark Law further demonstrates that McCollum, Oaktree, PMA, and Labsource knew that the employed physicians' compensation arrangements were required to comply with the Stark Law and that paying the physicians amounts that were directly tied to the volume and value of their UDT referrals was unlawful.

192. Nevertheless, at all relevant times, with the full knowledge of McCollum, Oaktree, PMA, and Labsource, physicians received compensation that varied with and took into account the volume or value of their UDT referrals to Oaktree and Labsource.

193. Indeed, McCollum, Oaktree, and Labsource tracked the UDT referrals generated by each physician on various spreadsheets throughout the relevant time period. Some of these spreadsheets were used by McCollum and other management-level employees to calculate the physicians' compensation.

194. Moreover, in or around 2017 and through 2018, McCollum and other PMA management-level employees met with individual Oaktree physicians to discuss their collection amounts and to explain the new 2017 compensation/bonus structure. During these meetings, McCollum and other PMA management-level employees told Oaktree physicians that they could make more money if they ordered more UDT, ordered more pain injection procedures, and prescribed more lidocaine ointment.

195. Thus, throughout the relevant time period, Oaktree physicians understood that a portion of their compensation was directly based on collections for their UDT referrals to Oaktree and Labsource. As such, Oaktree physicians were financially incentivized to order more UDT, regardless of whether those tests were medically necessary for an individual patient or not.

196. Throughout the relevant time period, Oaktree physicians were never provided a choice as to where to send their UDT referrals. Rather, the PMA clinics—with McCollum's

knowledge and at his direction—made the decision to send all of the Oaktree physicians' UDT referrals to Oaktree and Labsource. Indeed, by mid to late 2016, the PMA clinics, with McCollum's knowledge and direction, began referring most of its Medicare UDT to Labsource after CMS placed Oaktree under a payment suspension for billing medically unnecessary UDT.

197. Throughout the existence of these compensation arrangements, McCollum and other PMA and Labsource management-level employees knew that physicians were making DHS referrals to Oaktree and Labsource, for which Oaktree and Labsource submitted claims to, and received payments from, Medicare.

198. Despite their knowledge of these Stark Law violations, and throughout the relevant time period, Defendants McCollum, Oaktree, and Labsource, expressly and falsely certified compliance with the Stark Law on CMS-855B provider enrollment forms and CMS 1500 forms and their electronic equivalents.

II. McCollum and Labsource Violated the AKS

199. During the relevant time period, Defendants McCollum and Labsource knowingly and willfully offered providers remuneration designed, at least in part, to induce referrals of UDT paid for by Medicare, Medicaid, and TRICARE.

A. Oaktree's Compensation Arrangements with Physicians and Other Providers Violated the AKS

200. McCollum established and perpetuated a scheme to offer remuneration to Oaktree providers (e.g., physicians, physician assistants, and nurse practitioners), who were not Labsource employees, based, in part, on their referrals to Labsource.

201. Specifically, McCollum offered and paid Oaktree physicians, physician assistants, and nurse practitioners bonuses based, in part, on their referrals to Labsource.

202. At least one purpose of these remuneration schemes was to induce referrals to Labsource, including referrals of UDT reimbursed by federal health care programs.

203. Paragraph 190 above provides some examples of Oaktree physicians who received bonuses, paid directly or indirectly by Labsource, based on their UDT referrals to Labsource in violation of the AKS. The following table provides examples of Oaktree mid-level providers who, at various times from 2013 to December 31, 2018, received bonuses, paid directly or indirectly by Labsource, based on their UDT referrals to Labsource in violation of the AKS:

Provider	Approx. Dates Provider Eligible for Bonus Based on UDT Referrals to Labsource	Estimated # of Medicare Claims for UDT for Labsource	Estimated Medicare Payments to Labsource for UDT
Carol Ann Berry, F.N.P.	1/1/2011 to 12/31/2018	1,570	$432,977
Carlee Bright, P.A.	9/15/2011 to 2/31/2017	1,239	$355,790
James Goodson, P.A.	3/20/2014 to 2/6/2016	229	$58,525
Jill Kessler, F.N.P.	1/1/2011 to 12/31/2017	964	$296,804
Derek Roper, P.A.	1/4/2013 to 12/31/2018	956	$242,095
Brant Turner, P.A.	8/30/2011 to 12/31/2018	1850	$564,219
Jessica Wright, F.N.P.	05/1/2017 to 7/17/2018	601	$177,333

204. McCollum and Labsource acted knowingly and willfully in offering and providing Oaktree providers with inducements to refer UDT to Labsource payable by Medicare, Medicaid, and TRICARE.

205. For example, McCollum and other PMA management-level employees repeatedly informed Oaktree providers that if they wished to make more money, they needed to make UDT referrals. For example, in an email to Oaktree physician assistant Carlee Bright on May 23, 2017, McCollum wrote, in pertinent part:

> As we discussed in our meeting last week, ***one of my goals for 2017 is to pay you more money.*** In order to get there, I need your help watching a few things each day and they are:
>
> . . .
>
> ***UDS % - (weekly goal is 45%) - You are doing a great job. Watch for your high risk patients that probably need to be tested monthly or bi monthly*** . . . . (Emphasis added).

206. From at least 2014 to at least December 31, 2018, Labsource routinely transferred money to Oaktree that was used to pay Oaktree providers in exchange for their referrals. McCollum's scheme, through Labsource, to pay Oaktree providers—including physicians, nurse practitioners, and physician assistants—based, in part, on their UDT referrals to Labsource violated the AKS. The *bona fide* employee exception and safe harbor to the AKS, described above, does not apply here, as the referring providers were not employees of Labsource.

207. Throughout the existence of these unlawful remuneration schemes, Oaktree providers referred UDT to Labsource in violation of the AKS, as a result of which Labsource submitted thousands of claims to Medicare, Medicaid, and TRICARE that were ineligible for payment.

B. Labsource's Direct Bill Program Violated the AKS

208. From 2014 through at least December 31, 2018, Labsource, at McCollum's direction, utilized kickbacks—in the form of a "direct bill" program—as a means to grow its business.

209. Under the direct bill program—sometimes referred to by McCollum or others as the "client bill" program—Labsource provided referring providers with an opportunity to earn revenue generated from their commercially-insured UDT referrals as an inducement for those providers to refer all of their UDT, and specifically for Medicare, Medicaid and TRICARE beneficiaries, to Labsource.

210. Courts have repeatedly held that giving providers "the opportunity to earn more money," as Labsource did through its direct bill program, is a thing of value that constitutes remuneration under the AKS. *United States v. Addus HomeCare Corp.*, No. 13-CV-9059, 2017 WL 467673, *10 (N.D. Ill. Feb. 3, 2017); *see also United States v. Bay State Ambulance and Hosp. Rental Service, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989) ("Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."); *United States ex rel. Fry v. Health Alliance,* No. 1:03–CV–00167, 2008 WL 5282139, at *7–*8 (S.D. Ohio Dec.18, 2008).

211. In general, the laboratory performing the UDT bills the insurer for the tests it performs. By contrast, Labsource's direct bill program functioned as follows:

a. A participating provider—either an individual physician or a clinic—would execute a direct bill agreement with Labsource.
b. The participating provider would then pay Labsource a modest negotiated fee (typically between $200 and $250) for each commercially-insured UDT order referred to Labsource.
c. Labsource, in turn, would permit the provider to stand in Labsource's shoes and

bill the commercial insurer for the UDT performed by Labsource, and retain as profit the difference between the commercial insurance reimbursement and the negotiated fee paid to Labsource.

d. However, Labsource would bill and retain all of the revenue generated by Medicare, Medicaid and TRICARE referrals.

212. In the spring of 2014, McCollum sought to grow Labsource by bringing in a new sales force and utilizing the direct bill program as a sales tactic.

213. In or around the spring of 2014, McCollum, through his business partner, Dean Banks, contacted Joe Case, then the head of sales at Castle Medical, LLC, a competing UDT laboratory, which already had its own direct bill offering.

214. In or around June 2014, McCollum met with Case and one of his Castle Medical sales executives, Scott Massey, in an effort to recruit them to work for Labsource. During those early discussions, McCollum made clear his interest in growing the business at Labsource. McCollum brought up the direct bill concept and specifically inquired about Case's and Massey's familiarity with it. Case and Massey walked McCollum through the direct bill offering and how it should work.

215. In or around June 2014, after meeting with McCollum and other senior members of the Labsource team, Case and Massey agreed to join Labsource. The two quickly went about recruiting other sales representatives over to Labsource, including a number of their former colleagues at Castle Medical.

i. Utilizing the Direct Bill Program to Induce Referrals—Including Medicare, Medicaid, and TRICARE Referrals—to Labsource

216. From the very beginning, McCollum and Labsource viewed the new direct bill program, which was modeled on Castle Medical's direct bill offering, as a way to develop referrals and revenue from certain federal health care programs. For example, on June 19, 2014, Donna Rauch, then serving as Chief Operating Officer of McCollum's PMA business, sent an

email to McCollum, Case, Massey, and another Labsource executive, summarizing plans for the direct bill program. Her e-mail stated, in pertinent part, "Commercial amounts will go to the customer's bank account. . . . The M[edi]care and M[edi]caid billed through Labsource will come directly to Labsource." On that same date, Massey forwarded the summary to three of the new sales representatives, noting, in pertinent part, "Keep these details to FYI as we prepare to roll this out but here is what the details of DB Billing option will be." *Id.*

217. Shortly thereafter, McCollum himself set about promoting Labsource's new direct bill program. On July 9, 2014, he wrote an e-mail to a prospective client in Irmo, South Carolina, explaining how, under the direct bill program, the provider could earn money from referring definitive UDT to Labsource. The e-mail stated, in pertinent part:

> Paul,
>
> Thank you for getting the statistics to me. I have asked Scott Massey, Divisional Vice President of South Carolina, to stop by your office and discuss our recommendations with you. . . . On the confirmation (quantitative) side, I recommend that you consider a direct bill, aka client bill, arrangement with us. This would allow you to capture $300-$400 per sample on your confirmations.

218. McCollum, Case, and Massey next turned their focus to training the newly hired sales representatives. In or around July 2014, Joe Case, with input from McCollum and others, put together a training agenda, which he then e-mailed to McCollum, Massey, and other Labsource executives. The agenda succinctly described what was to be Labsource's strategy for selling to providers: "Get them to the $." Indeed, in discussions related to the upcoming training, McCollum and Case specifically discussed pitching direct bill as a business opportunity for providers that set Labsource apart from the competition.

219. Case and Massey then prepared a PowerPoint presentation for use at the sales training. In or around July and early August 2014, McCollum, along with other senior Labsource executives, reviewed and provided input for that presentation.

220. The presentation, which was subsequently utilized during the sales representative training, described different tactics sales representatives could use in order to help providers earn more money as an inducement for doing business with Labsource. Chief among these tactics was the new direct bill program.

221. The presentation described the direct bill program as "a way to introduce a substantial revenue stream into the clinic." The presentation explained that direct bill "can in fact land you some HUGE clinics . . . . It is recommended that you utilize this as an enticement for doing business with us." The presentation made clear that sales representatives should utilize tactics like the direct bill program to "[g]et in front of the decision maker" at a provider's office: "Get past the gatekeeper by asking the questions that offer the clinic a cost savings or an additional profit center." The presentation concluded by instructing sales representatives to offer direct bill as "as an Additional Benefit of Doing Business with Us," but cautioned them to expect the following questions: "Is it Legal" and "Is it Too Good to be True."

222. The sales representative training itself took place in Greenville, South Carolina, on or around August 6, 2014. McCollum provided some brief remarks at the training and, according to several attendees, remained present for all or most of the training that followed.

223. Case delivered much of the training, along with Massey. As part of that training, Case utilized the presentation described above. According to an audio recording of the training, Case provided clear direction regarding how sales representatives were to pitch Labsource to providers.

224. At the beginning of the training, Case provided the following roadmap:

> ***So what you're going to see for the next three hours is the way I go about the sales process—is get them to the money.*** Physicians are struggling today. They are all looking for additional income streams, so you are going to see how I go about getting them to the money. (Emphasis added).

225. Case reiterated that theme later in the training: "Everything I do—I'm trying to make the physician more money. You [i.e., Labsource] get money off of confirmations."

226. Case explained his sales approach, encouraging Labsource's new sales representatives to emphasize direct bill early in their sales pitches, both as a way to get the provider's attention and as a crucial strategy for closing sales:

> [I]f I'm in front of an anesthesiologist, and he tells me, you know, "I only got a couple minutes. I got a patient back on my fluoro." That means he's going in to do an injection. ***That tells me I don't have a lot of time, so what I'm going to do, in that scenario is, I'm going to introduce who I am; I'm going to talk about Labsource really quick and I mean really quick; and I'm going to go right to direct bill.***
>
> ***Because if I can show him how to put a half million dollars in his pocket, that table—that table is going to be sat on for quite some time while he listens to Joe talk*** [. . . .] If you're in a doctor's office and you can grab an hour, that's great. Don't plan on getting it. ***Plan on about 15 minutes, if you're lucky. Okay. But when you can actually speak to the money, and show them how you can bring them profit, you'll be amazed at how long you get.*** Scott Massey has put me on the phone a couple times. One was a guy in Virginia Beach, probably never gave anyone more than five or ten minutes. ***He gave me an hour-and-a-half, and when I got off the phone, the sale was made, because Millennium*** [i.e., a competing UDT laboratory] ***didn't have me, and I showed that guy how to put money in his pocket. Okay. So it makes a big difference when you're talking about the financial side of it.*** This was our game-changer, and this is what helped me grow market share like no tomorrow. (Emphasis added).

227. According to the audio recording, Case emphasized the importance of direct bill as a way to close sales—describing sales efforts with the direct bill program as "shooting fish in a barrel"—but also cautioned sales representatives that they should expect "objections" from the providers about the legality of the direct bill program:

> ***I'm showing [the provider] how to pull in a $700 return off doing the same thing [the provider is] currently doing. Who [is the provider] going to go with? It's us. That's been the experience of direct bill.*** Okay. I'm going to go into a lot more in detail, into a spreadsheet, on that, and then you can ask your questions and more. ***But basically, past your billing, direct bill—when I get done explaining this to you, there's going to be two objections you're going to receive from the office manager and the physicians. Is it legal [and] it's too good to be true. If you learn how to get through those two objections, you can sell this all day long***. This is shooting fish in a barrel, and I'm not kidding you. . . . This is the gold nugget. (Emphasis added).

228. According to the recording, Case also emphasized the importance of lucrative federal health care program referrals to Labsource—describing them as "bread and butter"—given that Labsource would only earn, at most, $250 for commercially insured patients under the direct bill program: "Last year Medicare reimbursed, roughly, at $700. They've reduced my units this year. I'm probably making 550. Medicaid gets me about 325. Okay. That's my bread and butter, because I'm only making 250 off commercial."

229. Case underscored this point when explaining the benefit to Labsource of direct bill arrangements with providers who had a payor (i.e., patient insurance) mix dominated by federal health care programs—specifically, Medicare and Medicaid. While the provider would not earn money from referrals to Labsource for Medicare and Medicaid patients under the direct bill program, Labsource certainly would:

> Payor mix comes into play here to. Let's say [a provider's] . . . payor mix is 90 percent Medicare/Medicaid. Well, good for us. It's great for us. What you consider payor mix, your normal train of thought, is actually good for me. It's not as good for the clinic. A lot of things that I introduce, through our sales process, is to benefit the clinician and bring them value, and income, at the clinical level. So a bad payor mix in ours, is actually good for Labsource, because that means he's doing less commercial, and I'm eating more Medicare. I can make a living off Medicare, guys.

230. In the course of the training, Case indicated that McCollum would be available to help close sales: "If you've got a big fish out there or you've got a big deal you're working, Dr. McCollum is usually available."

231. As noted above, McCollum was present for all or much of the training. At no point during the training did he object to, question, or seek to clarify the training and instructions provided by Case to Labsource's sales representatives.

232. The training made a strong impression on many of the attendees about the importance and efficacy of direct bill as a way to induce referrals to Labsource. For example, Brian Jaffe—who was invited by an acquaintance to attend the training even though he was not yet a Labsource employee—testified that he was so impressed by the training and Labsource's direct bill program that he decided to work for the company:

> So then the [direct bill] concept that they presented to me was, like, wow, this is really—why would somebody not want to buy this? I was, like, I'm in, I'm in.
>
> . . . .
>
> Instead of the [toxicology] companies taking all the revenue, the doctors could take a portion of the revenue. Okay. So I'm thinking why would—if a doctor makes nothing and then all of a sudden they can make a lot of money, . . . why would they not do that. . . . So I was, like, this is too good to be true. . . . So I went to Phoenix, and I started working the Phoenix market.

233. Many Labsource sales representatives followed the direction provided at the training and led with direct bill in their sales pitches, using the remuneration available to providers under the direct bill program as a way to induce UDT referrals, including Medicare, Medicaid, and TRICARE UDT referrals.

234. For example, in or about late August 2014, Jaffe, who became a Labsource sales representative after the August 2014 training, used the following language in an e-mailed sales pitch sent to a prospective client:

> What's different about Lab[s]ource is that not only do we use state of the art LCMS technology to help you monitor over 50 therapeutic drugs, **we enable you to capture significant additional revenues to your facility.**
>
> I know you are incredibly busy, but I would welcome the opportunity to meet with you or a member of your team for 15 minutes to discuss how Lab[s]ource can improve Decision Point Center's drug monitoring programs **while significantly growing your bottom line.** (Emphasis in original)

235. On October 7, 2014, another Labsource sales representative wrote an e-mail to a potential client to "just touch on some of the major aspects of what Labsource can bring to your clinic." The e-mail proceeded to describe, *inter alia*, the direct bill program—referring to it as "Client Bill." The sales representative explained, "The average reimbursement for the total test is between $600–700. We . . . split the revenue between Labsource and your clinic."

236. On November 20, 2014, another Labsource employee wrote to a prospective client, copying one of Labsource's divisional vice presidents of sales, and attaching documents regarding Labsource. One attachment, under heading titled "Why Labsource?," touted the "revenue sharing" available to the provider under the direct bill program. The attachment included a pro forma estimating that the provider could earn income of $125,000 per month under the direct bill program, by referring 500 definitive tests to Labsource.

237. Another Labsource sales representative wrote the following in an e-mailed sales pitch to a prospective client on December 15, 2014: "We hope that you will consider us working together in a partnership in which we can offer the following: Direct Bill . . . . If you do 500 confirmations per month, you would realize a net profit of $125,000/month."

238. Jaffe also testified as to the exchange he generally had when pitching Labsource to prospective clients—one in which direct bill figured prominently:

> So basically, what I would say is—I would say, "So, Doctor, are you currently prescribing opiates?" And if the answer is no, that would be it. There was no more.
>
> And if they said yes, "Okay. Are you testing your patients, doing urine drug screening?"
>
> And if they say "no," then I would talk about the importance of urine drug screening and how, you know, there's a greater opioid epidemic in the country and you're putting your patients at risk by not doing it.
>
> If they say yes, "Who are you using?"
>
> "I'm using Millennium."
>
> "Oh, great. How do you like them?"
>
> "Oh, they're fine."
>
> "Let me ask you a question, Doctor. How much money are you making on your urine drug screening?"
>
> "Excuse me?"
>
> "Yes. We have a special program called direct bill, and how it works is that instead of the lab billing the insurance company and the lab taking all the revenue, we allow you to bill the insurance company. And so you bill them for 3-, $400, we bill you for 180, and you make the difference. And, you know, $100, $150 or whatever the net profit . . . you're talking $15,000 a month."
>
> "Where do I sign?"

239. McCollum was actively involved in Labsource's direct bill program from its launch in 2014 throughout the relevant time period. In addition to his role in launching the program at Labsource, he occasionally participated in sales pitches—either in person or by telephone. Case, who overheard a few of those pitches, testified that McCollum would refer to the direct bill program as an opportunity for the providers to make a significant income stream.

McCollum also played an active role in managing the program and signed many of the direct bill agreements with providers on behalf of Labsource.

240. McCollum also played an active role in determining the fee that Labsource would charge a given provider for commercially insured patients under the program. As noted above, these fees typically ranged from $200 to $250. Those providers for which other laboratories were competing often received lower fees. This, in turn, made the direct bill program even more profitable for those providers.

241. As noted above, federal health care program referrals were greatly valued by Labsource. In particular, Labsource considered Medicare to be one of the most reliable and consistent payors. In addition, Labsource could often earn far more in profits from federal health care program reimbursement than from the modest fees Labsource negotiated with providers for commercially insured referrals under the direct bill program. For example, according to internal Labsource correspondence, during the summer of 2015, Labsource expected to receive reimbursement of $340 from Medicare for a typical panel of tests—substantially more than $200–$250 fee Labsource received for each commercially insured urine specimen referred under the direct bill program. At about that same time, Labsource estimated that it could incur on average close to $200 in costs in running tests on a given specimen. Labsource therefore earned little, if any, profit on the negotiated fees for commercial referrals from direct bill clients and earned all, or most of its profit, from those clients' federal health care program referrals. Put another way, the direct bill program made the most economic sense for Labsource if it resulted in federal health care program referrals. As Case accurately noted during the August 2104 sales training, Medicare and Medicaid were his "bread and butter."

242. Consistent with this, Labsource prioritized providers with large federally insured patient populations. Indeed, before offering a direct bill arrangement to a prospective client, Labsource analyzed the payor mix for that provider's patient population to determine the percentage of that provider's patients who had federal health care program insurance, as opposed to commercial insurance, workers' compensation, or no insurance.

243. Moreover, a number of former Labsource sales representatives and senior sales executives testified that Labsource offered the direct bill program to providers with the specific goal that providers would refer to Labsource *all* of their UDT business, specifically including their Medicare, Medicaid, and TRICARE referrals. In seeking to obtain *all* of a provider's referrals, specifically including those "bread and butter" federal health care program referrals, these individuals sought to maximize earnings for Labsource, maximize their own sales commissions, and/or prevent a competing laboratory from gaining a foothold with a client.

244. For their part, providers responded favorably to Labsource's direct bill pitch. According to Labsource sales representatives, many providers selected Labsource over the competition due to the remuneration offered by the direct bill program. For example, as one former Labsource sales representative acknowledged in an e-mail to Joe Case: "The entire reason Rush Pain began sending samples to LabSource was to build a 'slush' fund to fund the initial start up for" their own laboratory development efforts.

245. Similarly, Jaffe testified that his sales pitch "close rate" was very high and explained that the direct bill program played a significant role in that:

> Because the drug screening business is very, very competitive. There's many players out there. Some much larger than Lab[s]ource. And so doctors typically don't like change. And so if they are satisfied with a current provider, they're going to let it go. So there has to be some sort of impetus to make them change. And that [direct bill program] really drove

> the impetus. That was the driving factor was the ability to make revenue, make money on that.

246. During the relevant time period, according to Labsource, at least 179 providers from around the country—including Oaktree—entered into direct bill arrangements with Labsource. These providers referred a large number of Medicare, Medicaid, and TRICARE UDT orders to Labsource, resulting in tens of thousands of claims submitted to those federal health care programs—including well over $10 million of tests insured by Medicare alone—pursuant to those direct bill arrangements.

247. For example, Dr. Gregory Auzenne, who, according to Labsource, had a direct bill agreement in place from approximately August 2014 through December 2015, referred a significant number of Medicare-insured UDT orders to Labsource during that time. Medicare paid Labsource over $860,000 for those direct bill referrals. Dr. Gregory Stynowick, who, according to Labsource, had a direct bill agreement in place from approximately June 2014 through August 2016, referred a significant number of Medicare-insured UDT orders to Labsource during that time. Medicare paid Labsource over $310,000 for those direct bill referrals. Similarly, Dr. Alexander Beyzer, who, according to Labsource, had a direct bill agreement in place from approximately June 2014 through March 2015, referred a significant number of Medicare-insured UDT orders to Labsource during that time. Medicare paid Labsource over $160,000 for those direct bill referrals. Notably, none of these providers had referred any Medicare-insured orders to Labsource prior to entering into their direct bill agreements.

248. The *bona fide* employee exception and safe harbor to the AKS, described above, does not apply here because the referring providers were not employees of Labsource.

249. Labsource and McCollum acted knowingly and willfully in offering the direct bill program as an inducement for obtaining Medicare, Medicaid, and TRICARE referrals to Labsource.

250. For example, as predicted during the August 2014 sale training, providers frequently questioned the legality of Labsource's direct bill program. Scott Massey, who went on to serve as Labsource's head of sales after Joe Case, testified as follows: "It was always a legality question. Most physicians were very concerned, will this get them in trouble."

251. Labsource responded to those provider questions by obtaining and sharing with prospective clients a series of attorney opinion letters. The attorney opinion letters were drafted by Labsource's outside counsel, Yussuf Aleem. The letters all followed the same general format, with some modifications to reflect the laws of the state in which a given provider was located. Each such letter purported to explain why the direct bill program complied with the AKS, the Stark Law, and certain state laws, though as Massey noted in his testimony, "[T]he keyword there is it's an opinion. That was not in any way like, okay, it's permissible now. No, that doesn't give you any assurance."

252. If anything, the attorney opinion letters put Labsource on notice that its conduct was, indeed, illegal. In particular, the attorney opinion letters each noted that their analysis "relie[s] solely on the facts presented to [Mr. Aleem]" by Labsource; the letters proceed to identify the following as one such the "fact[]" relied upon by Mr. Aleem: "[Labsource] will not provide anything of value, whether directly or indirectly, in order to induce Providers to refer specimens from patients who are insured through Government Payors." But as illustrated above, contrary to the representations Labsource made to its attorney, Labsource and McCollum did indeed offer the direct bill program as way to provide value to providers—in the form of

commercial insurance revenue—to induce those providers to refer to Labsource all of their of their UDT business, specifically including UDT payable by Medicare, Medicaid, and TRICARE.

III. McCollum, PMA, Oaktree, Labsource, ProLab, and ProCare Submitted, or Caused the Submission, of Medically Unnecessary Claims to Medicare, Medicaid, and TRICARE

253. The unlawful financial incentives detailed above ultimately resulted in the submission of medically unnecessary claims to Medicare, Medicaid and TRICARE. Specifically, McCollum, PMA, Oaktree, and Labsource submitted, or caused the submission, of medically unnecessary UDT claims to those federal health care programs. As detailed below, ProLab and ProCare also submitted, or caused the submission of, medically unnecessary UDT claims to Medicare, Medicaid, and TRICARE. McCollum, Oaktree, and PMA also submitted or caused the submission of medically unnecessary claims to those federal health care programs for steroid injections and prescription drugs—specifically, opioids and lidocaine ointment that were medically unnecessary and unreasonable and lacked a legitimate medical purpose. Defendants submitted, or caused the submission of, these claims with knowledge that they were medically unnecessary—or at least in reckless disregard of that fact.

A. Defendants McCollum, PMA, Oaktree, Labsource, ProLab, and ProCare Knowingly Submitted, or Caused the Submission, of Claims to Medicare, Medicaid, and TRICARE for Medically Unnecessary UDT and/or UDT that was not Performed

i. Medically Unnecessary UDT for PMA Patients

254. As described below, McCollum, PMA, Oaktree, and Labsource took proactive steps that resulted in providers ordering medically unreasonable and unnecessary UDT across PMA's patient population. Moreover, in some instances, Oaktree and Labsource submitted claims, and were paid, for UDT that was not actually performed.

255. During certain office visits with providers, PMA patients were asked to provide a urine sample for testing. For at least a portion of the relevant time period, the provider performed a presumptive POC test at the PMA clinic and ordered definitive UDT that, at the direction of McCollum and PMA, were sent to Oaktree or Labsource. Oaktree or Labsource performed a presumptive immunoassay test and definitive UDT on the urine samples sent by the PMA clinic.

256. McCollum, PMA, and Oaktree caused providers to routinely order excessive UDT for their patients—without an individualized assessment of which tests were actually necessary for a given patient—by utilizing a default UDT panel established by Oaktree. Although the components of Oaktree's default UDT panel changed periodically between January 1, 2011, and December 31, 2018, Oaktree providers were not given options regarding whether or not to use the default panel or what specific tests to include in the panel. In addition, the default panel included presumptive immunoassay testing. Moreover, the results of a patient's presumptive test (POC and/or immunoassay) were not used in determining whether to run definitive UDT. Rather, Oaktree performed definitive UDT using this default panel on a routine basis, even in situations where the presumptive tests were negative and consistent with clinical expectations. Oaktree's default UDT panel was often comprised of 15 or more different definitive drug tests, including for substances that were not commonly abused by PMA's patient population or had low risk for abuse or diversion. These practices resulted in UDT that was medically unreasonable and unnecessary, which Oaktree billed to Medicare, Medicaid, and TRICARE.

257. From approximately 2011 through 2016, Oaktree received payment from Medicare alone in excess of $586,000 for UDT involving phencyclidine ("PCP") (CPT Code 83992). PCP is not a commonly abused drug, and PMA rarely had patients who used or tested

positive for PCP. Dr. Bert Blackwell, PMA's medical director, testified that he would not choose to include PCP on a definitive UDT panel, given the option. Yet, Oaktree consistently included PCP on its default UDT panel and billed such testing to Medicare, Medicaid, and TRICARE.

258. Similarly, in 2014, Oaktree's default UDT panel included Tricyclic Anti-Depressants ("TCAs"), despite the fact that TCAs present a low risk of abuse and diversion and that not all PMA patients were prescribed and/or taking TCAs. In that year, Oaktree received payment from Medicare alone in excess of $332,800 for UDT of four types of TCAs: amitriptyline (CPT Code 80152), desipramine (CPT code 80160), doxepin (80166), and nortriptyline (CPT Code 80182).

259. In or around mid-2013, PMA clinics began referring UDT to McCollum's other laboratory, Labsource. The determination whether to send UDT to Oaktree or Labsource depended largely on reimbursement rates by payors to each laboratory. On September 15, 2015, Michael Brohm, PMA's CEO at the time, e-mailed PMA and Labsource management-level employees, including McCollum, recommending that PMA patients' urine samples be processed and billed by Labsource for Medicare, Medicaid, and TRICARE because Labsource was reimbursed at a higher rate than the Oaktree. By mid to late 2016, PMA began referring most of its Medicare UDT to Labsource after CMS placed Oaktree under a payment suspension for billing medically unnecessary UDT.

260. Similar to Oaktree, Labsource created a default UDT panel often comprised of presumptive immunoassay testing and 20 more different definitive tests that was used across all PMA patients regardless of individual patient need and billed to Medicare, Medicaid, and TRICARE.

261. Notably, the Oaktree and Labsource default UDT panels were often large enough to result in the highest levels of reimbursement from Medicare and TRICARE, even after the 2016 changes to UDT reimbursement. *See supra* Paragraph 148.

262. By including presumptive immunoassay tests and numerous definitive tests on their default UDT panels and preventing physicians from ordering fewer than all of those tests, McCollum, PMA, Oaktree, and Labsource knowingly submitted, or caused the submission, to Medicare, Medicaid, and TRICARE of tens of thousands of claims for millions of dollars of medically unreasonable and unnecessary UDT during the relevant time period.

263. The determination as to which tests Oaktree and/or Labsource performed on a particular patient's urine specimen was not based on the patient's clinical history, risk of abuse, or individual clinical assessment, but rather driven exclusively by whatever default UDT panel was in effect at that time.

264. For example, PMA Patient B.P.,[1] a Medicare beneficiary, was seen on February 3, 2012 by Dr. Ryan Rosen. Patient B.P. was an established PMA patient who was being treated for neck, back, hip, and knee pain. Patient B.P. had no history of alcohol or drug abuse. According to the medical record, Patient B.P. did not have a history of non-compliance or aberrant behavior. On February 3, 2012, a presumptive POC test was performed for Patient B.P. and tested positive for opiates and benzodiazepines, which was expected and consistent with Patient B.P.'s prescribed medications. The requisition/order form indicated "Comprehensive Drug Monitoring-Urine." However, the ordering physician did not select or specify exactly

[1] Patient identities are not provided here to protect patient privacy. Upon entry of an appropriate protective order, the United States will provide Defendants with a list identifying the names of the patients described in this Complaint.

which drugs the laboratory was to perform definitive testing. Moreover, the medical necessity of ordering such definitive testing was not clearly stated in the medical record.

265. Oaktree performed definitive UDT on B.P.'s specimen for numerous drugs. The patient medical record did not support the need for such extensive definitive testing and there was no documentation in any follow-up visits of a review of the results of this definitive testing performed by Oaktree. The results of the definitive UDT were reported as inconsistent with the patient's prescribed medications. Specifically, the definitive UDT listed a positive result for Tramadol which was not found listed in the medical record as one of the patient's prescribed medications. This unexpected positive result was not addressed by the treating physician. Nor is there any indication in the patient file of any modification in treatment based on the results of the definitive testing. Oaktree submitted claims to Medicare for Patient B.P's UDT and was paid over $840 for these tests. Oaktree also submitted a claim to Medicare for UDT of alcohol, but there is no indication in the medical record that such testing was actually performed. Medicare paid Oaktree an additional $14.02 for this test. Oaktree knew these claims for tests that were not reasonable and necessary and, in some instances not performed, were false.

266. As another example, PMA Patient K.F., a Medicare patient, was seen on June 16, 2014 by physician assistant, Brant Turner. Patient K.F. was an established PMA patient who was being treated for knee pain. Patient K.F. had no history of alcohol or drug abuse. On June 16, 2014, presumptive POC UDT was performed for patient K.F. and tested positive for opiates, which was expected and consistent with K.F.'s prescribed medications. PMA then sent Patient K.F.'s urine specimen to Oaktree with a requisition/order form indicating "Pain/addiction pnl w/scrn." The requisition/order form did not specify which drugs should receive definitive testing.

267. In accordance with the default UDT panel in effect at the time, Oaktree conducted a presumptive immunoassay screen and definitive UDT on K.F.'s for numerous different drugs. The results of Patient K.F.'s presumptive test were not used in determining whether to run definitive UDT. Rather, the definitive UDT panel appeared to be routine and not based on the results of Patient K.F.'s presumptive test or any patient specific risk assessment. Nothing in the patient file supported the need for such extensive definitive UDT. The definitive UDT results were appropriately positive for hydrocodone (and its metabolites) and clonazepam, which Patient K.F. had been prescribed. However, the definitive UDT did not detect Tramadol, another one of Patient K.F.'s prescribed medications. There was no documentation or discussion of this inconsistency on the follow-up visit nor was there any modification of treatment based on the results of this testing. Oaktree submitted claims to Medicare for this UDT for Patient K.F. and was paid over $701 for these claims. Notably, over $141 of these claims were for definitive UDT of tricyclic anti-depressants (e.g., amitriptyline, desipramine, nortriptyline, and doxepin), nicotine, and alcohol when there was no indication in the medical record that such tests were actually performed. Oaktree knew these claims for tests that were not reasonable and necessary and, in some instances not performed, were false.

268. As another example, PMA Patient S.K., a dual-eligible Medicare and Medicaid beneficiary, was seen on August 24, 2015, by Oaktree physician Dr. Dwight Jacobus. Patient S.K. was an established PMA patient who was being treated for chronic pain. The medical record indicated that Patient S.K. had no history of drug or alcohol abuse and no history of non-compliance or aberrant behavior. On August 24, 2015, presumptive UDT was performed and was positive for oxycodone and benzodiazepines, which was consistent with Patient S.K's prescribed medications. PMA then sent Patient S.K.'s urine specimen to Labsource with a

requisition/order form indicating "Automated Panel." The requisition/order form did not specify as to which drugs the laboratory was to perform definitive testing.

269. Labsource conducted presumptive immunoassay testing and definitive UDT for numerous drugs on Patient S.K.'s urine specimen. The results of Patient S.K.'s presumptive test were not used in determining whether to run definitive UDT. Rather, the definitive UDT panel appeared to be routine and not based on the results of Patient S.K.'s presumptive test or any patient specific risk assessment. There was no indication that the treating clinician assessed the medical need, if any, of those tests. Labsource submitted claims to Medicare for this testing for Patient S.K. and was paid $245. Labsource knew these claims for UDT that were not reasonable and necessary were false.

270. McCollum, PMA, Oaktree, and Labsource engaged in the described conduct above despite knowing that testing should be based on individual patient need. For example, in or around April 2014, while serving as the laboratory director of Labsource, Dr. Marion Snyder shared with McCollum and other Oaktree providers a presentation she drafted titled "Proposed Urine Toxicology Ordering Protocol." In the presentation, Dr. Snyder referenced a recent draft LCD issued by Palmetto GBA and emphasized that "confirmatory testing should **ONLY** be ordered and performed on a patient/drug specific basis[.]" (Emphasis in original). She also noted in the presentation that "routine confirmation (quantitative) of drug screens with negative results is not covered by Medicare."

271. PMA also ordered UDT more frequently than was medically reasonable and necessary. As noted above, McCollum and Oaktree kept track of how much UDT was being ordered by Oaktree providers and set targets or goals for each provider and PMA clinic to meet. For example, in August 2016, Tommy Jackson, the COO of PMA at the time, emailed PMA

clinic managers, urging certain offices to increase the amount of UDT ordered: "FANTASIC job on [UDT] to everyone! If you are below 30% please catch up with the rest of the offices. (You know who I am talking too [sic])." Moreover, in or around 2017, McCollum implemented a UDT policy by which Oaktree providers were each assigned a particular month. All patients seen by that provider during his or her assigned month were to receive a UDT regardless of individual need.

272. There were numerous instances during the relevant time period in which both Oaktree and Labsource billed Medicare for UDT performed on a single PMA patient on the same day or within a few days of one another. This testing was duplicative and medically unreasonable and unnecessary.

273. For example, on October 29, 2014, Oaktree billed Medicare for UDT referred by Oaktree physician, Dr. Brian Bothe, for Patient J.K. Two days later, on October 31, 2014, Labsource billed Medicare for the exact same urine drug tests for Patient J.K. Medicare paid Oaktree and Labsource approximately $440 each for those tests.

274. As another example, on February 19, 2014, Oaktree billed Medicare for UDT referred by Oaktree physician, Dr. Dwight Jacobus, for Patient P.F. On the very same day, Labsource billed Medicare for many of the same urine drug tests for Patient P.F. Medicare paid Oaktree and Labsource—approximately $335 and $210, respectively—for those duplicative tests.

ii. Medically Unnecessary UDT for PMA Patients Involving ProCare and ProLab

275. In or around 2013, McCollum and PMA entered into a business relationship with ProCare, whereby McCollum and PMA agreed to allow individuals employed by ProCare

("ProCare greeters") into PMA clinics to promote ProCare's substance abuse and addiction counseling services.

276. ProCare greeters provided PMA patients with ProCare "gift cards" that could be redeemed for free counseling sessions at ProCare.

277. The ProCare counseling sessions purportedly educated patients on the proper way to use opioid medications prescribed by Oaktree physicians. The ProCare counseling sessions were also purportedly used to ensure that the patients were not abusing their opioid medications or at risk for negative drug interactions.

278. Patients who were seen at ProCare were required to provide a urine sample that was sent off for testing at McCollum's and ProCare's laboratory, ProLab.

279. ProCare's medical director and only employed physician was Dr. William Scott. Pursuant to his medical director agreement with ProCare, Dr. Scott's duties included, but were not limited to, "signing of all charts and labs."

280. As noted above, pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."

281. Dr. Scott was designated on ProLab's claim forms as the ordering and referring physician for the vast majority of patients for whom ProLab performed and billed UDT. However, by his own admission and contrary to the requirements of 42 C.F.R. § 410.32(a), Dr. Scott never actually saw or treated a single patient at ProCare. Accordingly, all of the UDT referred to ProLab by Dr. Scott for ProCare patients—which resulted in thousands of claims

submitted to Medicare, Medicaid, and TRICARE—was neither reasonable nor medically necessary. In 2014, ProLab received over $598,000 from Medicare alone for UDT referred by Dr. Scott.

282. Similar to Oaktree and Labsource, ProLab utilized a default UDT panel established by the laboratory across most, if not all, of its patients without regard to individual need. This default UDT panel was often comprised of numerous different tests, including for substances that were not commonly abused and/or had low risk for abuse or diversion. The determination as to which tests ProLab performed on a particular patient's urine specimen was not based on the patient's clinical history, risk of abuse, or individual clinical assessment, but rather driven exclusively by whatever default UDT panel was in effect at that time.

283. Moreover, ProCare's orders for UDT were needlessly duplicative—often occurring on the same day or within several days of the date on which an Oaktree physician also ordered overlapping UDT for the same patient that was sent by PMA to another of McCollum's laboratories.

284. For example, on April 15, 2014, Oaktree, Labsource, and ProLab each billed Medicare for some of the same urine drug tests for Patient B.N. Although Medicare denied Labsource's claims, Medicare paid Oaktree and ProLab approximately $504 and $374, respectively, for those duplicative UDT claims.

285. By way of another example, on July 30, 2014, Oaktree and ProLab each billed Medicare for some of the same urine drug tests for Patient K.M. Medicare paid Oaktree and ProLab approximately $489 and $437 respectively, for those duplicative claims.

286. As yet another example, on August 5, 2014, Labsource billed Medicare for urine drug tests referred by Oaktree physician Dr. Rebecca Holdren for Patient M.N. Less than one

week later, on August 11, 2014, ProLab billed Medicare for many of the same urine drug tests for Patient M.N. supposedly ordered by Dr. William Scott of ProCare Counseling. Medicare paid Labsource and ProLab approximately $247 and $118, respectively, for those duplicative UDT claims.

287. For all the aforementioned reasons, the UDT ordered by ProCare and performed and billed by ProLab were completely devoid of medical necessity, and were merely another scheme for McCollum and his companies to unlawfully generate revenue from UDT.

iii. Medically Unnecessary UDT for Other Patients

288. In addition to serving Oaktree providers, Labsource offered both immunoassay and definitive UDT to other providers throughout the United States. As described below, during the relevant time period, Labsource took proactive steps to encourage providers to routinely order large quantities of medically unreasonable and unnecessary UDT across all or most of their patients—without an individualized assessment of which tests were actually necessary for a given patient—by utilizing standing order forms and the direct bill kickback scheme described in Section II.B., above. This practice resulted in thousands of claims for medically unreasonable and unnecessary UDT that was billed to Medicare, Medicaid and TRICARE.

289. As described above, when processing specimens for Oaktree providers, Labsource used a default UDT panel. When working with non-Oaktree providers, Labsource took a slightly different approach—encouraging medically unreasonable and unnecessary testing through the use of provider standing orders. Labsource obtained these standing orders through the use of its Physician's Preferred Order form ("PPOF"). Labsource created this form as part of its plan to direct providers to establish protocols for UDT to be performed on all of their patients—usually involving, at minimum, dozens of definitive tests—regardless of the patients' individual need.

290. Beginning in or around 2013, Labsource directed its sales force to obtain these standing orders from all of its provider clients. The "New Account Form" filled out by sales representatives for each new provider featured a reminder to "COMPLETE PHYSICIAN[']S STANDING ORDER FORM (*_*EXTREMELY IMPORTANT*_)." (Emphasis in original.) A revised version of the "New Account Form," developed in or around December 2014 and used, with some minor modifications, throughout the relevant time period, included the same reminder but referred to the form as "Physician[']s Preferred Order Form," rather than a "Standing Order Form."

291. Consistent with this direction, when signing up new providers, Labsource sales representatives encouraged each provider to fill out a PPOF. Each physician's standing order was then assigned a code. When the provider wished to order UDT from Labsource, the provider could simply reference the assigned code for his or her standing order, rather than selecting individual tests that were actually reasonable and necessary for a given patient.

292. Through its PPOF protocol, Labsource caused providers to utilize the same standing order of tests for all or most of their patients each and every time they requested UDT for those patients, resulting in frequent, overbroad, and unnecessary testing.

293. Indeed, through the use of its direct bill kickback scheme, described above, Labsource offered referring providers a powerful financial incentive to order UDT that was not medically necessary.

294. For example, Patient B.W. was a patient of Dr. Arie Mantin at Clemmons Urgent and Primary Care. Dr. Mantin had a direct bill agreement in place with Labsource. Patient B.W. had suffered a motorcycle accident resulting in a clavicle injury, shoulder pain, and ongoing chronic back pain. The patient was being treated with Suboxone. Every two weeks, Dr. Mantin

performed presumptive tests on the patient. Each of these presumptive tests came back as expected, indicating use of Suboxone, but showing no indication that the patient used any other drugs of abuse. Consistent with these results, Dr. Mantin described the patient as compliant with the therapy in the patient file. Despite these results, every two weeks, Labsource ran definitive testing on Patient B.W.'s urine specimens. For example, on October 3, 2014, Dr. Mantin referred B.W.'s urine specimen to Labsource for a broad standing order of 37 definitive tests. Medicare paid Labsource $416.79 for this testing alone. Nothing in the patient file supports the need for such definitive testing, and there is no documentation in any follow-up visits of a review of this or any other definitive testing performed by Labsource. Nor is there any indication in the patient file of any modification in treatment based on the results of this or any other definitive testing.

295. McCollum was involved in and aware of Labsource's standing order practice. For example on July 3, 2013, a Labsource employee copied McCollum on e-mail to a provider, which stated, in pertinent part, "Attached is the standing order form and all other pdf copies of the other essential reference service engagement materials." Similarly, on or around June 30, 2014, McCollum received an e-mail chain in which Corrine Fantz, a Labsource employee, reported that she "spoke with [a provider] this morning by phone. He verbally agreed to have his standing order revised to Screen for THC and EtG/EtS and ONLY confirm positives for these compounds. ***All other requests will be confirmed by LC-MSMS*** [i.e., definitive testing] ***regardless of screening result***." (Emphasis added). On or around July 1, 2014, McCollum replied to the e-mail chain, stating "Excellent work Corinne!"

296. In or around 2014, Labsource took steps to further encourage physicians to order medically unreasonable and unnecessary UDT through their standing orders by revising the

format of the PPOF. Rather than listing each test individually, the revised PPOF grouped Labsource's presumptive and definitive test offerings into "profiles." For example, although these profiles changed to some extent over time, at various points in time during the relevant time period, Labsource offered a "Basic Confirmation Profile," a panel consisting of over 40 individual tests; an "Extended Confirmation Profile," a panel consisting of over 50 individual tests; and an "Extended Confirmation Profile with Pyschotherapeutics," a panel consisting of 70 or more individual tests. Notably, the Labsource-created profiles were all large enough to result in the highest levels of reimbursement from Medicare and TRICARE, even after the 2016 changes to UDT reimbursement. *See supra* Paragraph 148.

297. Labsource proceeded to encourage providers to select these large panels of definitive tests as their standing order, for use on a routine basis—rather than simply performing definitive testing on positive or unexpected presumptive test results or otherwise testing based on individual patient need.

298. For example, on December 20, 2014, a Labsource sales representative e-mailed a provider, copying a Labsource divisional vice president of sales, and stating, in pertinent part,

> Hello Diane,
>
> Please review the New Account information for accuracy and make any necessary corrections. All we need is the signed Physician Preferred Order and the Direct Bill Agreement. ***We recommend that you mark the basic confirmation profile under LC-MS/MS Quantitative Testing section unless you need Extended Confirmation PO40 or PO4***. . . . (Emphasis added).

299. That same sales representative sent an e-mail on January 12, 2015 to another provider—once again copying a divisional vice president of sales—and directing the provider to fill out the PPOF as follows: "Just check the basic confirmation and don't worry about the immunoassay section."

300. Similarly, on November 24, 2014, Scott Massey sent an e-mail to a sales representative, copying McCollum and other Labsource executives, stating as follows:

> Jeff,
>
> ***This account is only setup for screens (and confirm only positives)***[.] ***It needs to have a confirmation choice beyond just confirming positives***. If they want an immunoassay system that they run in house and send us the positives that's fine but we can't take screens only. ***It is a financial loser for us. I have attached the preferred order form. Please revise it so we can do confirms.*** Thanks[.] (Emphasis added).

301. Labsource's efforts to encourage the use of standing orders were successful. Jenny Jones, Labsource's former Vice President of Operations, acknowledged that when ordering UDT from Labsource, providers almost never deviated from their standing orders. Scott Massey similarly testified that "more often than not" providers used as their standing orders one of the Labsource-created profiles listed in the revised PPOF.

302. These tactics resulted in medically unreasonable and unnecessary testing.

303. For example, Patient B.A., a Medicare patient, who had a history of alcohol and nicotine dependence, was admitted to Turning Point Hospital for in-patient detox treatment. The patient self-reported no other substance use or abuse, and, around the time of admission, a presumptive test showed no use of non-prescribed drugs or substances of abuse. The facility provided a controlled environment for Patient B.A.—removing from the patient any possessions considered to put the patient at risk and providing medications in a hospital setting under the prescription and supervision of a treating provider. Despite the presumptive tests results and the use of this controlled environment, on August 21, 2014, the patient's date of discharge from that program, Labsource performed a broad profile of over 50 definitive tests, for which Medicare paid

$566.01. Nothing in the patient's file indicates the need for such testing, and nothing in the patient's file indicates that the results of such testing—which were consistent with the medications prescribed to the patient while at Turning Point—were ever reviewed or used in any way.

B. McCollum, Oaktree, and PMA Caused the Submission of Claims to Medicare, Medicaid, and TRICARE for Unnecessary Opioid Prescriptions That Lacked a Legitimate Medical Purpose

304. From at least January 1, 2011, through December 31, 2018, Oaktree providers, with McCollum's knowledge and approval, regularly wrote prescriptions for thousands of claims for opioid medications for PMA patients that were not for a medically accepted indication and therefore lacked a legitimate medical purpose and medical necessity.

305. Oaktree, PMA, and McCollum knowingly caused the submission of these false claims for opioid prescriptions for patients insured by Medicare, Medicaid, and TRICARE.

306. In many instances, Oaktree providers issued opioid prescriptions to PMA patients without actually seeing the patients and/or without properly assessing the patients' need for those drugs.

307. PMA employees used pre-signed and forged opioid prescriptions with patients when the patient's provider was not present. For example, Oaktree physician Dr. Blake Leche and physician assistant Amanda Leche provided PMA staff with pre-signed prescription forms, enabling the staff members to simply write in the opioid drug name and dosage when Dr. Leche was not present in the office or was otherwise unavailable to see the patient. In other instances, PMA staff simply forged Dr. Leche's signature on opioid prescriptions.

308. For example, Patient G.L. obtained a prescription for Norco (hydrocodone/acetaminophen), a Schedule II controlled substance, from Dr. Leche on April 9,

2018, despite the fact that there was no indication that Dr. Leche was in the office, much less that he saw the patient on that date. Medicare Part D paid approximately $15 for this forged/pre-signed prescription.

309. Similarly, former Oaktree physician, Dr. Christopher Rubel, often saw well over 70—and sometimes upwards of over 90—PMA patients a day. His interactions with these patients were often cursory in nature and frequently did not involve a substantive examination. Dr. Rubel nevertheless proceeded to prescribe opioids for PMA patients that were medically unnecessary and without a legitimate medical purpose.

310. Tracy Hawkins, who was Dr. Rubel's medical assistant from approximately October 2016 to August 2018, was tasked with filling out prescriptions for Dr. Rubel, including altering the dosage or type of opioid medication upon the patient's request. Dr. Rubel would then sign the prescriptions without adequately assessing the patient.

311. For example, Patient O.A. stated that Dr. Rubel spent no more than five minutes with her and never examined her. She indicated that on at least ten occasions she never saw a provider; instead, a medical assistant would simply hand her a prescription for OxyContin. From April 2016 to February 2018, Medicare Part D paid approximately $851 for OxyContin prescribed by Dr. Rubel for Patient O.A.

312. McCollum knew about the conduct described above, but nevertheless permitted his employees to continue writing these improper opioid medication prescriptions, including prescriptions that would be reimbursed by Medicare, Medicaid, and TRICARE. In a discussion with Oaktree nurse practitioner Jessica Wright, McCollum referred to his PMA clinics in Easley and Sklyn, South Carolina, as "pill mills," a term commonly used to describe a practice that is prescribing narcotics without a legitimate medical purpose.

313. Along those lines, McCollum and other PMA management-level employees were also specifically aware of Dr. Rubel's opioid medication prescribing habits and the attendant risks. Indeed, in or around December 2017, McCollum, along with PMA management-level employees Dawn Richards, and Michael Brohm, had a meeting with Jessica Wright, an Oaktree nurse practitioner who worked closely with Dr. Rubel. In the course of that meeting, McCollum acknowledged Dr. Rubel's excessive opioid prescribing habits and the recent overdose deaths of two PMA patients.

314. McCollum acknowledged during his conversation with Jessica Wright that he was aware that other Oaktree physicians, such as Dr. Dwight Jacobus and Dr. Brian Wiley, also prescribed excessive opioid medications to PMA patients.

315. McCollum did not take appropriate or sufficient steps to curb the prescription of medically unnecessary and illegitimate opioids at PMA. Instead, McCollum himself profited from these prescribing practices. From roughly 2011 through roughly May 2018, First Choice Pharmacy was located in one of PMA's office buildings at 1005 Grove Road, Greenville, South Carolina. During the relevant time period, a number of PMA patients seen by Oaktree providers filled their prescriptions at that pharmacy, including prescriptions for opioid medications they received from Oaktree providers. McCollum, in turn, received rent from the pharmacy, in the amount of roughly 2.5% of the pharmacy's gross sales (including sales of opioids).

C. McCollum and PMA Pressured and Incentivized Oaktree Providers to Perform Unnecessary Steroid Injection Procedures

316. McCollum and PMA also encouraged Oaktree physicians to administer medically unnecessary and unreasonable steroid injections to Medicare, Medicaid, and TRICARE patients addicted to pain medications and/or desperate for pain relief, who were vulnerable and unlikely

to object to the procedures, particularly when the injections were described as prerequisites for receiving opioid prescriptions.

317. As noted above, providers may, in certain circumstances, inject steroids into muscles and tendons, or into joints such as the spine (facet joints), knees, hips, elbows, or shoulders, for the purpose of decreasing inflammation in these areas. However, the frequent use of steroid injections may cause adverse events, including the weakening or necrosis of the area injected, nerve damage, or infection.

318. In closed-door meetings with Oaktree providers and during practice-wide meetings, McCollum and other PMA management-level employees communicated a practice goal that over 30% of patients seen each week should be receiving steroid injections, without regard to medical necessity and the risks of such procedures.

319. To incentivize Oaktree providers to refer or perform more steroid injection procedures, McCollum and PMA management-level employees frequently reminded physicians that their bonus included reimbursements from these injection procedures.

320. In or around 2017, McCollum also devised a scheme to circumvent the medical judgment of Oaktree providers entirely by having a non-licensed PMA staff member, Greta Meehan, call PMA patients and falsely tell them that their treating provider recommended an injection and that they would need to receive the injection in order to continue receiving pain medication prescriptions.

321. For example, PMA Patient R.W. was told that if he did not agree to receive injections, his medications would be discontinued. Moreover, PMA Patient L.N. was pressured to submit to steroid injections and feared if she did not undergo the procedures that her pain medication would not be refilled. Following the steroid injections, Patient L.N. experienced

trouble controlling her diabetes—a known side effect of steroid injections. Both Patient R.W. and Patient L.N. were insured by Medicare.

322. Greta Meehan scheduled many PMA patients for procedures with Oaktree physician Dr. Lisa Lichota, an interventional pain specialist, who, upon learning of the scheme, repeatedly voiced her concern to Daniel McCollum and Dr. Bert Blackwell.

323. In an e-mail sent to McCollum on September 5, 2017, Dr. Lichota stated, in pertinent part:

> To Dr McCollum,
>
> Please do not have Gret[]a schedule procedures for me unless I first see the patient. When Dr Blackwell asked if I would do procedures that a "colleague" ordered I agreed to do so. As far as I know Gret[]a is not a physician nor a midlevel. I am unaware if she is a medical clinician of any sort. I am unaware what credentials she holds. I have requested her CV but I have not received one. I believe that she is scheduling procedures based on x-ray reports that have not been read by a qualified physician. They all seem to report the same findings. "DJD, injections may be indicated." The physician, [nurse practitioner], [or physician assistant] that saw the patient hasn't recommended the procedure that is being scheduled for me . . . . Thus, there is no clinical correlation to the x-ray reports. ***These patients show up on my surgical schedule. They have told me that if they don't agree to the procedure, their medication will be stopped. They seem to have no idea what is going on except that a woman unknown to them has called them and told them they need to come in for an injection and that if they do not, their medications will be stopped.*** (Emphasis added).

324. Between June 1, 2017, and October 16, 2017, the period when Meehan was actively scheduling patients for injections, Medicare paid approximately $90,482 for injections procedures performed by Lisa Lichota. At least a portion of these were performed based on Dr. Lichota's understanding that a licensed provider had ordered the injections, when in reality, the injections were scheduled by unlicensed PMA staff.

325. For example, FirstChoice Healthcare submitted claims to Medicare for Patient C.H. for an epidural steroid injection given on August 11, 2017. This injection was not ordered

by a physician or mid-level provider, but instead was scheduled by Greta Meehan, who had little, if any, medical training. Relying on the certifications supplied by FirstChoice Healthcare as part of its claim submission, Medicare paid over $592 for Patient C.H.'s epidural steroid injection claims. Had Medicare known that the procedure was performed without a valid order by the treating provider, it would not have paid this claim.

326. In or around 2017, Oaktree Physician Assistant Carlee Bright learned that several of her patients received injections before she had the opportunity to review the patient's diagnostic images, determine clinical need, and/or discuss the risks and benefits associated with the particular injection. Bright learned from several patients they were contacted by Greta Meehan to schedule the injection procedure, and the patients were told that Bright ordered the injection, when in fact, she did not. Meehan also informed Bright's patients, as she did Dr. Lichota's patients, that they would have to receive the injection before they could receive their pain medication prescription.

327. Bright testified that when she voiced concern about this practice to McCollum and/or PMA management-level employee Dawn Richards, she was simply told, "Yeah, that's the plan."

328. As a result of this scheme perpetrated by McCollum, Oaktree, and PMA hundreds of PMA patients received medically unreasonable and unnecessary injections, many of which were billed to and paid by Medicare, Medicaid, and TRICARE.

329. McCollum and PMA's pressure tactics and practice of strong arming patients to submit to these procedures worked. In 2016, Medicare paid FirstChoice Healthcare over $421,000 for steroid injection procedures. In 2017, the amount paid by Medicare to FirstChoice Healthcare for steroid injection procedures increased to over $1.8 million. Further, by 2018, the

amount paid to FirstChoice Healthcare by Medicare for steroid injection procedures increased to $2.2 million.

D. McCollum, Oaktree, and PMA Pressured and Incentivized Oaktree Providers to Prescribe Unnecessary Lidocaine Ointment That Lacked A Legitimate Medical Purpose

330. In or around May 2014, McCollum, Oaktree, and PMA identified another opportunity to generate substantial revenue through prescription ointments that were medical unnecessary and lacked a legitimate medical purpose. To capitalize on this opportunity, McCollum formed a pharmacy, Exigo Pharmaceuticals, LLC ("Exigo"), which was located inside of one of the PMA office buildings. Exigo focused on producing ointments containing lidocaine, a topical anesthetic.

331. Because lidocaine ointments are, at most, only marginally useful for patients experiencing chronic pain, McCollum devised a two-part scheme in order to generate revenue from insurance reimbursement. First, McCollum, Oaktree, and PMA incentivized Oaktree providers to prescribe these ointments by offering them compensation in exchange for each prescription filled by Exigo. Second, he had Exigo automatically ship refills to patients—many of whom never even discussed the need for use of the ointments with their providers.

332. As noted above, on May 23, 2017, McCollum e-mailed Oaktree Physician Assistant Carlee Bright writing, in pertinent part, "one of my goals for 2017 is to pay you more money. In order to get there, I need your help watching a few things each day[.]" Among these "things" he identified was a "goal" of 20 lidocaine ointment prescriptions per week. He also instructed her to include 11 refills in each prescription.

333. In addition, as part of a January 2017 presentation titled "Who Moved My Cheese," which was given to Oaktree providers, Dr. Blackwell detailed the compensation those

providers could expect to earn by prescribing these ointments. Specifically, in a slide titled "Provider Compensation Compound Rx's," he explained: "For the month of October 104 Rx's were written (one prescriber accounts for 38). Collected $37,750. If the provider prescribing 38 rx's in the month of October averaged this the rest of the year, this would result in an additional $33,100 paid to the provider."

334. In order to further drive the prescription of lidocaine ointment, beginning in or around 2017, PMA employee Nicole Poston reviewed patient records for payor information to determine which patients had insurance that would pay for the lidocaine ointment. Based on Poston's analysis, PMA issued daily memoranda to Oaktree providers, indicating which patients had appointments that day and whether or not their insurance would cover the lidocaine ointment.

335. McCollum and other PMA management-level employees used these daily memoranda to encourage Oaktree providers to prescribe lidocaine ointment for all patients with qualifying insurance. For example, on January 12, 2018, McCollum e-mailed a number of Oaktree providers, instructing them to write more lidocaine ointment prescriptions based on Poston's insurance analysis. He stated, in pertinent part,

> I would like to ask that you please pay very close attention to the Lidocaine sheets that you receive on a daily basis. We have contributed a tremendous amount of time and resources to compiling this list on a daily basis and ***I would like to see more compliance with the schedule. Since implementing the process, we have seen our Lidocaine numbers increase; however, we are still missing more than 100 prescriptions per day when compared to what is actually eligible***. ***I have attached this week***[']***s spreadsheet of missed prescriptions and I would ask that you and your team pay close attention to this and help capture these lost opportunities***. I will be sending this spreadsheet out weekly and meeting with you individually to discuss any specific concerns or feedback. (Emphasis added).

336. McCollum, Oaktree, and PMA knew that these schemes would cause Oaktree providers to write prescriptions for lidocaine ointment, including prescriptions reimbursed by Medicare, Medicaid, and TRICARE, that were not medically necessary and were without a legitimate medical purpose. And that is precisely what happened.

337. PMA patients began receiving prescription lidocaine ointments in the mail, although many of these patients never had any discussion with their medical provider about the necessity, risks, or uses for the lidocaine ointment. Moreover, these patients were never even given a choice of pharmacy; they simply received deliveries of the ointments from Exigo.

338. For example, Patient L.N., who was regularly treated by Nurse Practitioner Carol Ann Berry at PMA's Myrtle Beach, South Carolina, clinic location, began receiving tubes of lidocaine 5% ointment delivered to her home between May 2017 and November 2017, with a label indicating that the product came from Exigo in Easley, South Carolina. Patient L.N. had never discussed the need for lidocaine with her provider, was not given the opportunity to fill the prescription at a pharmacy of her choice, had never heard of Exigo, and did not know how the medication was to be used. Medicare Part D paid a total of $3,845 pursuant to 10 false claims made by Exigo for Patient L.N. for lidocaine 5% ointment between May 2017 and January 2018.

339. As another example, Oaktree, PMA, and McCollum caused numerous false claims to South Carolina Medicaid for lidocaine 5% ointment shipped to Patient F.K. Patient F.K. was bedridden and did not have use of his arms or his legs. Patient F.K. visited a PMA office on no more than two occasions and was told by the provider that the provider could not help him with his pain. Following the appointment, Patient F.K. began receiving packages from Exigo each month containing between ten and eleven tubes of lidocaine 5% ointment. Patient F.K. never discussed the need for lidocaine with the provider he saw, was not given the

opportunity to fill the prescription at a pharmacy of his choice, had never heard of Exigo, and did not know how the lidocaine was to be used. South Carolina Medicaid paid a total of $2,148.24 for Patient F.K. pursuant to nine false claims made by Exigo for lidocaine 5% ointment between November 2017 and June 2018.

340. This scheme proved costly for federal health care programs. Altogether, Medicare Part D, TRICARE, and South Carolina Medicaid paid approximately $5,428,433 for lidocaine ointment prescriptions filled by Exigo between 2014 and 2018, the vast majority of which were medically unnecessary and not prescribed for a legitimate medical purpose:

	Total Paid to Exigo for Lidocaine	**Total Claims**	**Dates**
Medicare Part D	$ 3,886,746.95	8,698	04/09/2015 to 09/19/2018
TRICARE	$ 298,914.00	876	01/01/2014 to 08/08/2018
Medicaid	$ 1,242,772.00	5,213	11/25/2014 to 12/31/2018

FIRST CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: Presenting and Causing False Claims – Stark Law Violations (31 U.S.C. § 3729(a)(1)(A))

341. The United States re-alleges incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

342. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to

the Medicare program for UDT furnished by Oaktree and Labsource that was referred by Oaktree physicians in violation of the Stark Law.

343. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

344. The United States sustained damages because of this wrongful conduct.

SECOND CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: False Statements and Records Material to False Claims – Stark Law Violations
(31 U.S.C. § 3729(a)(1)(B))

345. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

346. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

347. These false records and statements included false certifications on Medicare provider enrollment forms and false and misleading representations on claim forms that claims for UDT submitted to Medicare by Oaktree and Labsource complied with the Stark Law, when, in fact, those claims violated the Stark Law.

348. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

349. The United States sustained damages because of this wrongful conduct.

THIRD CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: Conspiracy– Stark Law Violations
(31 U.S.C. § 3729(a)(1)(C))

350. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

351. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, Labsource, and their co-conspirators entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the Medicare program—and/or made, used, and caused to be made or used false records or statements in support of those claims—for UDT furnished by Oaktree and Labsource that was referred by Oaktree physicians in violation of the Stark Law.

352. The defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, compensating Oaktree physicians directly based on the volume and value of UDT referrals and other business generated (e.g., private pay and non-Medicare UDT referrals) by those physicians for Oaktree and Labsource, and then submitting or causing the submission to Medicare of claims for UDT resulting from those referrals, in violation of the Stark Law.

353. The defendants and their co-conspirators submitted; made or used; or caused to be submitted, made, or used such false claims, records, and/or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

354. The United States sustained damages because of this wrongful conduct.

FOURTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: Presenting and Causing False Claims – Remuneration to Oaktree Providers in Violation of the AKS
(31 U.S.C. § 3729 (a)(1)(A))

355. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

356. During the relevant time period, Defendants McCollum and Labsource knowingly and willfully offered and paid remuneration to Oaktree providers—including physicians, physician assistants, and nurse practitioners—to induce them to refer UDT (including UDT payable by federal health care programs) to Labsource, in violation of the AKS.

357. The defendants then filed or caused the filing of claims to Medicare, Medicaid, and TRICARE for that UDT, which claims were false because they violated the AKS. 42 U.S.C. § 1320a-7b(g).

358. The defendants presented or caused to be presented such claims for UDT with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

359. The United States sustained damages because of this wrongful conduct.

FIFTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: False Statements Material to False Claims – Remuneration to Oaktree Providers in Violation of the AKS
(31 U.S.C. § 3729(a)(1)(B))

360. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

361. During the relevant time period, Defendants McCollum and Labsource knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

362. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for UDT submitted by Labsource to Medicare, Medicaid, and TRICARE complied with the AKS, when, in fact, those claims violated the AKS because McCollum and Labsource provided remuneration to Oaktree providers to induce the providers to refer UDT to Labsource, including UDT payable by federal health programs.

363. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

364. The United States sustained damages because of this wrongful conduct.

SIXTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: Conspiracy – Remuneration to Oaktree Providers in Violation of the AKS
(31 U.S.C. § 3729(a)(1)(C))

365. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

366. During the relevant time period, Defendants McCollum, Labsource, and their co-conspirators knowingly entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to federal health care programs, including claims for reimbursement to Medicare, Medicaid, and TRICARE—and/or made, used, and caused to be made or used false records or statements in support of those claims—for UDT referred to Labsource by Oaktree providers in violation of the AKS.

367. The defendants and their co-conspirators submitted; made or used; or caused to be submitted, made, or used such false claims, records, or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

368. The defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, offering and paying remuneration to Oaktree providers to induce them to refer UDT (including UDT payable by federal health programs) to Labsource, and then submitting or causing the submission to Medicare, Medicaid, and TRICARE of claims for UDT resulting from those referrals, in violation of the AKS.

369. The United States sustained damages because of this wrongful conduct.

SEVENTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: Presenting and Causing False Claims - AKS Violations Involving Direct Bill Program
(31 U.S.C. § 3729 (a)(1)(A))

370. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

371. During the relevant time period, Defendants McCollum and Labsource knowingly and willfully offered and provided remuneration to providers through Labsource's "direct bill" program by agreeing to assign to those providers the right to bill commercial insurers for UDT performed by Labsource, and at least one purpose of this remuneration was to induce those providers to refer UDT payable by federal health programs—including Medicare, Medicaid, and TRICARE—to Labsource, in violation of the AKS.

372. The defendants then submitted or caused the submission to Medicare, Medicaid, and TRICARE of claims for payment for that UDT, which claims were false because they violated the AKS. 42 U.S.C. § 1320a-7b(g).

373. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

374. The United States sustained damages because of this wrongful conduct.

EIGHTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: False Statements Material to False Claims - AKS Violations Involving Direct Bill Program
(31 U.S.C. § 3729(a)(1)(B))

375. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

376. During the relevant time period, Defendants McCollum and Labsource knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

377. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for UDT submitted by Labsource to Medicare, Medicaid and TRICARE complied with the AKS, when, in fact, those claims violated the AKS because McCollum and Labsource provided remuneration to providers through the direct bill program, at least one purpose of which was to induce the providers to refer UDT to Labsource, including UDT payable by federal health programs.

378. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

379. The United States sustained damages because of this wrongful conduct.

NINTH CAUSE OF ACTION
Against McCollum and Labsource:
False Claims Act: Conspiracy - AKS Violations involving Direct Bill Program
(31 U.S.C. § 3729(a)(1)(C))

380. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

381. During the relevant time period, Defendants McCollum, Labsource, and their co-conspirators knowingly entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to federal health care programs, including

claims for reimbursement to Medicare, Medicaid, and TRICARE—and/or made, used, and caused to be made or used false records or statements in support of those claims—for UDT referred by providers in violation of the AKS. In particular, through the "direct bill" program, McCollum and Labsource offered and provided remuneration to providers in the form of assigning them the right to bill commercial insurers for UDT performed by Labsource, at least one purpose of which was to induce them to refer UDT (including UDT payable by federal health programs) to Labsource, in violation of the AKS.

382. The defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, entering into "direct bill" agreements with providers and assigning them the right to bill commercial insurers for UDT that was actually performed by Labsource, and submitting or causing the submission to Medicare, Medicaid, and TRICARE of claims for UDT referred to Labsource by those providers, in violation of the AKS.

383. The defendants and their co-conspirators submitted; made or used; or caused to be submitted, made, or used such false claims, records, or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

384. The United States sustained damages because of this wrongful conduct.

TENTH CAUSE OF ACTION

Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable UDT Furnished By Oaktree and Labsource
(31 U.S.C. § 3729 (a)(1)(A))

385. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

386. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource knowingly presented

and/or caused to be presented materially false and fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs for medically unnecessary and unreasonable UDT performed by Oaktree and Labsource.

387. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

388. The United States sustained damages because of this wrongful conduct.

ELEVENTH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: False Statements Material to False Claims – Medically Unnecessary and Unreasonable UDT Furnished By Oaktree and Labsource
(31 U.S.C. § 3729(a)(1)(B))

389. The United States incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

390. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

391. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for UDT furnished by Oaktree and Labsource that were billed to Medicare, Medicaid, and TRICARE were medically necessary and reasonable, when, in fact, that UDT was medically unnecessary and unreasonable.

392. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

393. The United States sustained damages because of this wrongful conduct.

TWELFTH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource:
False Claims Act: Conspiracy – Medically Unnecessary and Unreasonable UDT Furnished By Oaktree and Labsource
(31 U.S.C. § 3729(a)(1)(C))

394. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

395. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, Labsource, and their co-conspirators entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs—and/or made, used, and caused to be made or used false records or statements in support of those claims—for medically unnecessary and unreasonable UDT performed by Oaktree and Labsource.

396. The defendants and their co-conspirators made or caused to be made such false claims, records, or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

397. The defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, ordering, performing, or causing the ordering or performance of medically unnecessary and unreasonable UDT through the use of, inter alia, default laboratory test panels and standing orders, and by submitting and causing the submission

of claims to Medicare, Medicaid, and TRICARE that misrepresented the UDT as medically necessary and reasonable.

398. The United States sustained damages because of this wrongful conduct.

THIRTEENTH CAUSE OF ACTION
Against McCollum, ProCare, and ProLab:
False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable UDT Furnished by ProLab
(31 U.S.C. § 3729 (a)(1)(A))

399. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

400. During the relevant time period, Defendants McCollum, ProCare, and ProLab knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs for medically unnecessary and unreasonable UDT performed by ProLab.

401. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

402. The United States sustained damages because of this wrongful conduct.

FOURTEENTH CAUSE OF ACTION
Against McCollum, ProCare, and ProLab:
False Claims Act: False Statements Material to False Claims – Medically Unnecessary and Unreasonable UDT Furnished by ProLab
(31 U.S.C. § 3729(a)(1)(B))

403. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

404. During the relevant time period, Defendants McCollum, ProCare, and ProLab knowingly made, used, and caused to be made or used false records or statements material to

false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

405. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for UDT furnished by ProLab that were billed to Medicare, Medicaid, and TRICARE were medically necessary and reasonable, when, in fact, that UDT was medically unnecessary and unreasonable.

406. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

407. The United States sustained damages because of this wrongful conduct.

FIFTEENTH CAUSE OF ACTION
Against McCollum, ProCare, and ProLab:
False Claims Act: Conspiracy– Medically Unnecessary and Unreasonable UDT Furnished by ProLab
(31 U.S.C. § 3729(a)(1)(C))

408. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

409. During the relevant time period, Defendants McCollum, ProCare, and ProLab, and their co-conspirators entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs—and/or made, used, and caused to be made or used false records or statements in support of those claims—for medically unnecessary and unreasonable UDT performed by ProLab.

410. The defendants and their co-conspirators made or caused to be made such claims and/or false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

411. In addition, the defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, ordering, performing, or causing the ordering or performance of medically unnecessary and unreasonable UDT through the use of, inter alia, default laboratory test panels, standing orders, and UDT orders signed by a physician who did not actually treat any of the patients, and by submitting claims to Medicare, Medicaid, and TRICARE that misrepresented the UDT as medically necessary and reasonable.

412. The United States sustained damages because of this wrongful conduct.

SIXTEENTH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina:
False Claims Act: Presenting and Causing False Claims – Medically Unnecessary and Unreasonable Opioid and Lidocaine Prescriptions and Steroid Injections
(31 U.S.C. § 3729 (a)(1)(A))

413. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

414. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina knowingly presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs for opioid and lidocaine ointment prescriptions and steroid injections that were not reasonable and necessary for the diagnosis or treatment of individual patients and that lacked a legitimate medical purpose.

415. The defendants presented or caused to be presented such claims with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

416. The United States sustained damages because of this wrongful conduct.

SEVENTEENTH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina
False Claims Act: False Statements Material to False Claims – Medically Unnecessary and Unreasonable Opioid and Lidocaine Prescriptions, and Steroid Injections
(31 U.S.C. § 3729(a)(1)(B))

417. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

418. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the defendants' statements and actions.

419. These false records and statements included false or fraudulent prescriptions, false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for opioid and lidocaine ointment prescriptions and steroid injections were reasonable and necessary for the diagnosis or treatment of individual patients and had a legitimate medical purpose, when, in fact, the contrary was true.

420. The defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

421. The United States sustained damages because of this wrongful conduct.

EIGHTEENTH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina:
False Claims Act: Conspiracy – Opioid and Lidocaine Prescriptions and Steroid Injections (31 U.S.C. § 3729(a)(1)(C))

422. The United States incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

423. During the relevant time period, Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and their co-conspirators entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the Medicare, Medicaid, and TRICARE programs—and/or made, used, and caused to be made or used false records or statements in support of those claims—for opioid and lidocaine ointment prescriptions and steroid injections that were not reasonable and necessary for the diagnosis or treatment of individual patients and that lacked a legitimate medical purpose.

424. The defendants and their co-conspirators made or caused to be made such false claims, records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

425. The defendants and their co-conspirators performed acts in furtherance of these conspiracies, by, among other things, providing, writing prescriptions, and/or causing providers to provide or write prescriptions for opioid and lidocaine ointment prescriptions, and to administer steroid injections that were not reasonable and necessary for the diagnosis or treatment of individual patients and that lacked a legitimate medical purpose, and by submitting and causing the submission of claims to Medicare, Medicaid and TRICARE for these prescriptions and injections.

426. The United States sustained damages because of this wrongful conduct.

NINETEENTH CAUSE OF ACTION
Against Oaktree and Labsource:
Payment by Mistake – Stark Law Violations

427. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

428. This is a claim for the recovery of monies paid by the United States during the relevant time period to Defendants Oaktree and Labsource as a result of mistaken understandings of fact.

429. The United States paid Defendants Oaktree and Labsource for UDT services that were furnished pursuant to prohibited referrals from providers who had financial relationships with the defendants that did not comply with the Stark Law. The United States made these payments without knowledge of material facts and under the mistaken belief that the defendants were entitled to receive payment for such claims when they were not. The United States' mistaken beliefs were material to its decision to pay the defendants for such claims. Accordingly, the defendants are liable to make restitution to the United States of the amounts of the payments made in error to them by the United States.

TWENTIETH CAUSE OF ACTION
Against McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, Labsource, and ProLab:
Payment by Mistake – Medically Unreasonable and Unnecessary Services

430. The United States re-alleges and incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

431. This is a claim for the recovery of monies paid by the United States during the relevant time period to Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the

Carolinas, PMA of North Carolina, Labsource, and ProLab as a result of mistaken understandings of fact.

432. The United States paid these defendants for UDT and steroid injections that were not reasonable and necessary for the diagnosis or treatment of individual patients as required by Medicare, Medicaid and TRICARE. The United States made these payments without knowledge of material facts and under the mistaken belief that the defendants were entitled to receive payment for such claims when they were not. The United States' mistaken beliefs were material to its decision to pay the defendants for such claims. Accordingly, the defendants are liable to make restitution to the United States of the amounts of the payments made in error to them by the United States.

TWENTY-FIRST CAUSE OF ACTION
Against All Defendants:
Unjust Enrichment

433. The United States incorporates by reference all Paragraphs of this complaint set out above as if fully set forth here.

434. This is a claim for the recovery of monies by which Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, Labsource, ProCare, and ProLab have been unjustly enriched during the relevant time period at the expense of the United States.

435. By directly or indirectly obtaining government funds to which they were not entitled, the defendants each were unjustly enriched, and are liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor against Defendants as follows:

I. On the First, Second, and Third Counts under the False Claims Act, against Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

II. On the Fourth, Fifth, and Sixth Counts under the False Claims Act, against Defendants McCollum and Labsource, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

III. On the Seventh, Eighth, and Ninth Counts under the False Claims Act, against Defendants McCollum and Labsource, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

IV. On the Tenth, Eleventh, and Twelfth Counts under the False Claims Act, against Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, and Labsource, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

V. On the Thirteenth, Fourteenth, and Fifteenth Counts under the False Claims Act, against Defendants McCollum, ProCare, and ProLab, for the amount of the United States'

damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

VI. On the Sixteenth, Seventeenth, and Eighteenth Counts under the False Claims Act, against Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, and PMA of North Carolina, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are authorized by law, together with all such further relief as may be just and proper.

VII. On the Nineteenth Count for payment by mistake, against Defendants Oaktree and Labsource, for the damages sustained and/or amounts by which Defendants were paid by mistake or by which the defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

VIII. On the Twentieth Count for payment by mistake, against Defendants McCollum, Oaktree, FirstChoice Healthcare, PMA of the Carolinas, PMA of North Carolina, Labsource, and ProLab, for the damages sustained and/or amounts by which the defendants were paid by mistake or by which the defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

IX. On the Twenty-First Count for unjust enrichment, against all Defendants, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

X. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

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